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Prevention of Low Back Pain in the Military: A Randomized Clinical Trial

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14. ABSTRACT

The third year of the Prevention of Low Back Pain in the Military (POLM) clinical trial was successful. The research team was able to complete all Year 3 tasks in a timely fashion. Study recruitment was completed in the previous year, so follow-up data collection was the primary goal of Year 3. The study website (https://polm.ufl.edu) continued to be the platform for follow-up data collection during Year 3. The research team reported 3 platform presentations at a national physical therapy conference. In addition POLM related manuscripts were accepted for publication in *Mil Med*, *Eur Spine J* and *Med Sci Sports Exerc*. Our preliminary analyses suggest that the education intervention reduced negative beliefs about low back pain, while the core stabilization exercise program did not adversely affect sit-up performance, and in fact, was associated with a small improvement in sit-up performance. These data provide important short term evidence to support our hypotheses related to long term prevention of low back pain.

15. SUBJECT TERMS
Primary prevention; cluster randomized trial; low back pain; core stabilization; biopsychosocial;

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INTRODUCTION

Low back pain (LBP) is a musculoskeletal condition that accounts for significant pain and disability, and consumes substantial medical and occupational costs annually. Specific to the United States Armed Forces, LBP was the second most common reason to seek healthcare and affects over 150,000 active duty Soldiers annually (MSMR 2003). Soldiers in the U.S. Army with LBP have the highest risk of disability 5 years after their injury. Furthermore, a military review suggests that LBP was the most common condition bringing about a medical board, with lifetime direct compensation costs estimated to reach into the billions of dollars. Therefore, reduction of disability from LBP is a significant research priority for the military.

Reduction of disability from LBP has been divided into 2 separate phases – primary and secondary prevention. Primary prevention refers to interventions and strategies that are implemented before a low back injury occurs.[2] Primary prevention reduces LBP related disability by reducing the total number of people who eventually experience an episode of LBP. Secondary prevention refers to interventions and strategies that are implemented during the acute episode of low back injury, before chronic symptoms occur.[1] Secondary prevention reduces LBP related disability by reducing the number of people who eventually experience chronic disability from LBP. We are proposing an innovative approach to LBP prevention by combining primary and secondary prevention strategies that have the potential to limit the development of chronic LBP in Soldiers.

Objective/Hypothesis

The purpose of the Prevention of Low Back Pain in the Military (POLM) trial is to determine if a combined prevention program is more effective at limiting the development of chronic LBP when compared to the effects of individual evidence-based prevention programs, or a traditional exercise program.

Specific Aims

Specific Aim 1: We will determine if a combined prevention program consisting of core stabilization exercise program (CSEP) and psychosocial educational program (PSEP) prevents the development of chronic LBP. During advanced individual training (AIT), United States Army Soldiers who volunteer will be randomly assigned to receive 1 of 4 prevention programs. Soldiers will be followed monthly during the first 2 years following AIT to measure LBP occurrence and severity with a web-based data collection system managed at the University of Florida.

Specific Aim 2: We will determine if the CSEP results in favorable changes in specific core musculature associated with reducing LBP. The CSEP activates specific core musculature that is important in preventing LBP. We will use real-time ultrasound imaging to measure changes in core musculature that occur during AIT. We will also determine if the PSEP results in a favorable change in LBP beliefs. The PSEP educates individuals in an evidence-based, psychosocial approach to the management of LBP, which can potentially decrease the likelihood of experiencing chronic LBP. We will use a validated self-report questionnaire to measure Soldiers' LBP beliefs regarding outcome and management. We will measure LBP beliefs at the beginning and end of AIT (a 12-week period).

Relevance: The results of this study will have several immediate applications for Soldiers. The widespread incorporation of effective preventative strategies will certainly result in a substantial reduction of LBP in the military. Programs that effectively prevent the occurrence and severity of LBP would benefit the U.S. Armed Forces by improving the readiness of their Soldiers, reducing economic burden, and limiting disability among Soldiers. For example, an average

cost of $136.02 per LBP visit was calculated for 2004. A 40% reduction in the recurrence of LBP after completing the CSEP would generate a cost savings of $3,343,230 by the 4th fiscal year (approximately 1/5 of the total cost of LBP for one FY).

Low back pain prevention programs are necessary to reduce the impact of musculoskeletal injury in the United States Military. Low back injuries are a significant cause of disability in the United States Army. For example in the United States Military, LBP was the second most common reason to seek healthcare and affected over 150,000 active duty Soldiers. Soldiers in the United States Army with LBP have the highest risk of disability 5 years after injury and a review suggests that LBP was the most common condition bringing about a medical board, with lifetime direct compensation costs estimated to reach into the billions of dollars. Clearly, quality clinical research producing evidence related to LBP prevention is warranted for the United States Military.

Programs that effectively prevent the occurrence and severity of LBP would benefit the United States Military by improving the readiness of their Soldiers, reducing economic burden, and limiting disability among Soldiers.

BODY

As outlined in our SOW, Year 3 was dedicated to data management, collection of follow-up data, and beginning of dissemination of results. These tasks are outlined below:

Task 3: Data management and follow-up (Years 2 – 4)

- Collect onsite post-training measures (Completed Year 2)
  - Self-report measures
    - Measures of mental and physical function
    - Negative affect
    - LBP
  - Muscle function measures Multifidi
    - Transversus abdominus
    - Erector spinae
- Monitor for episodes of LBP through website (ongoing)
  - Soldier access through username and password
    - Complete episode questionnaire
    - Complete pain questionnaires
    - Complete beliefs and coping questionnaires
  - Monthly email to AKO email address to update profile
    - Complete episode questionnaire
    - Complete pain questionnaires
    - Complete beliefs and coping questionnaires
- Update and maintain web-based data management system (ongoing)
  - System checks and fixes
  - Error checks and fixes

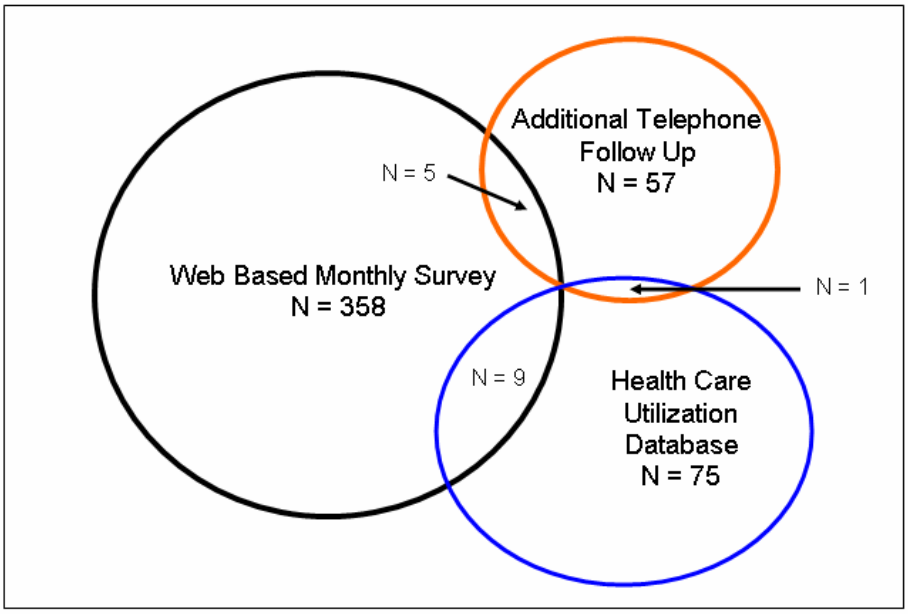
Follow-up is an important part of this study. Early results indicated that we were achieving adequate follow up through use of email and web-based responses only (Table 1).

Table 1. Summary for First Year Follow-Up

Treatment Group	Unique Survey Responses	# Responses with LBP	% LBP
Traditional Exercise	52	14	26.9%
Traditional Exercise and Education	76	18	23.7%
Core Stabilization	90	17	18.9%
Core Stabilization and Education	61	14	23.0%
Total	279	63	22.6%

To enhance follow-up rates, we elected to initiate phone contact with Soldiers to collect basic prevalence information about low back pain, and to encourage continued use of our web based data collection. We also gained access to a database that allows us to observe health care utilization data for low back pain for Soldiers enrolled in this study. These additional efforts provide us 3 sources of data to test our primary hypotheses related to prevention of low back pain. These sources will ensure we will have sufficient number of low back pain episodes to test our hypotheses (Figure 1).

Figure 1. Follow Up Summary by Reporting Source



There were a total of 505 episodes of low back pain reported: 372 from monthly survey; 85 from utilization data and 63 from the telephone sweep tool. A total of 57 additional episodes were picked up by telephone, in addition to the monthly survey and utilization data; and 75 additional episodes were picked up by the utilization data.

Task 4: Dissemination of research findings (Years 3 - 4)

- Analyze and report pre-training findings (Completed Year 3)
  - Scientific meeting (poster or platform presentation)
  - Manuscript submission
- Analyze and report post-training findings (Will be completed Year 4)
  - Scientific meeting (poster or platform presentation)
  - Manuscript submission
- Analyze and report final findings (Will be completed Year 4)
  - Scientific meeting (poster or platform presentation)
  - Manuscript submission

Dissemination of research findings for Year 3 occurred at the Combined Sections Meeting for the American Physical Therapy Association. POLM investigators reported original data at 3 platform presentations. Relevant content from these abstracts are reported below:

Abstract #1 - The Effects of Traditional Sit-Up Training Versus Core Stabilization Exercises on Sit-Up Performance in US Army Soldiers: A Cluster Randomized Trial (NCT00373009)

Purpose/Hypothesis

Despite longstanding tradition and widespread popularity of performing traditional sit-ups in the US Army, it has been postulated that this exercise results in increased lumbar spine loading, potentially increasing the risk of injury and development of low back pain (LBP). To address these potential concerns, health and fitness professionals commonly recommend performing "core stabilization" exercises, which have been shown to improve abdominal and trunk muscle

strength without the excessive loading incurred with traditional sit-ups, based on evidence that suggests core stabilization exercises may decrease the incidence of LBP and increase performance. However, core stabilization exercise programs (CSEP) have not been widely adopted in the US Army because of the perceived deleterious impact that failure to pass the Army Physical Fitness Test (APFT), which includes traditional sit-ups, can have on the Soldier's career. Therefore, the purpose of this study was to determine whether performing core stabilization exercises in lieu of traditional sit-ups would have detrimental effects on overall and sit-up scores and passing rates on the APFT.

Number of Subjects
2616

Materials/Methods
Subjects included healthy Soldiers between 18-35 years of age (or 17 year old emancipated minor) participating in Advanced Individual Training (N=2616) at Fort Sam Houston in San Antonio, TX. Soldiers with a previous history of LBP or other serious condition that precluded participation in physical training were excluded. History of LBP was defined as having met each of the following: 1) limited work or physical activity, 2) duration > 48 hours, and 3) resulted in seeking of medical care. Companies of Soldiers who were eligible and consented to the study were randomized to receive TEP with sit-ups or CSEP. A cluster randomization strategy was utilized for assigning companies to receive or not receive the CSEP since military training environments require living in close quarters with other members of the unit, making individual randomization unfeasible due to concerns related to disruption of normal training schedule and treatment contamination. TEP consisted of quick, high-load, high repetition exercises commonly included in military physical training and target the rectus abdominus, internal and external oblique, and hip flexor musculature. CSEP was comprised of slow, low-load exercises that involve minimal trunk motion and target the transverus abdominus and multifidi musculature. Soldiers completed their assigned exercise program during regularly schedules unit physical training 4 times per week over a 12-week training period. Training was led by the Soldiers' drill instructor. Performance on the AFPT was assessed every 4 weeks according to established Army standards. Descriptive statistics including measures of central tendency and dispersion were calculated to summarize the data. Independent variables were Group (CSEP and TEP), Quartile (0-25%, 26-50%, 51-75%, 76-100%), and Time (baseline, 12 wks). Dependent measures were overall and sit-up scores and passing rates on the APFT. We performed a 2×4×2 repeated-measures ANOVA with pairwise comparisons using the Bonferroni inequality to examine differences in the overall and sit-up scores on the APFT. Differences in overall and sit-up passing rates were assessed with a chi-square. The alpha-level was set to .05 a priori. Numbers needed to treat were assessed to determine the potential impact on decision-making.

Results
The mean age of participants was 21.9 ± 4.3 years of age (range: 17-35). Both groups performed sit-ups outside of unit physical training at equal rates (TEP: 69.5% and CSEP: 65%, P=0.067). There were no significant between group differences in overall scores (P=0.142) or sit-up performance (P=0.543) on the APFT after 12 weeks of training. CSEP and TEP improved their sit-up pass rates by 5.6% and 3.9%, respectively (P<.05). The NNT for CSEP was 56. Both groups demonstrated significant improvements in their overall and sit-up score and passing rates over time (P<0.05).

Discussion
CSEP did not have a detrimental impact on APFT scores or passing rates. There was actually a small but significantly greater increase in sit-up pass rate in the CSEP (5.6%) versus the TEP

(3.9%). Therefore, incorporating CSEP into Army physical training does not increase the risk of suboptimal performance on the APFT.

Conclusion
A company with 400 Soldiers performing CSEP would actually result in 7 additional Soldiers progressing from a failure to a pass on the sit-up component of the APFT compared to TEP.

Clinical Relevance
The results of this study help to inform the development of optimal training programs for Army physical fitness training.

Abstract #2 - The Influence of Sex, Height and Weight on Trunk Muscle Thickness and Endurance

Purpose
Trunk muscle strength and endurance may have an important role in the prevention and treatment of low back pain (LBP). Direct assessment of trunk muscle function is not feasible. Therefore, muscle morphometry has been used as an indirect measure. The purpose of this study was to describe how sex, height, weight, and body mass index (BMI) influence trunk muscle thickness and endurance times. and to provide reference data for trunk muscle size and symmetry in Soldiers.

Subjects
Soldiers (N = 190, 144 males, 46 females, 21.6 ± 4.0 years; 24.7 ± 2.9 kg/m^2) attending combat medic training at Fort Sam Houston, TX without a history of LBP were enrolled.

Materials/Methods
Ultrasound images were obtained bilaterally at rest for the following trunk muscles: rectus abdominis (RA), transversus abdominis (TrA), internal oblique (IO), and external oblique (EO), and lumbar multifidis (LM) at L4-L5. The following 4 endurance tests were assessed: supine flexor endurance test, prone extensor endurance test, and right and left horizontal side support. Independent t-tests were performed to determine if muscle thickness, muscle symmetry, or endurance times differed based on sex. Pearson product moment correlations were performed to determine the associations between height, weight, and BMI with muscle thickness values. Sex and weight were included in regression analysis to determine their contribution to the variance in trunk muscle thickness. Finally, sex, weight, and muscle thickness values were included in a regression analysis to determine their contribution to the variance in endurance times.

Results
Overall, muscle thickness was greater in males than females ($p < 0.006$). However, the TrA accounted for 10% of total abdominal muscle thickness regardless of sex. Muscle symmetry ranged from 6.6%-19.8% but did not differ based on sex ($p > 0.34$). Asymmetry was > 12% for the lateral abdominal muscles. Weight had a stronger correlation ($r = 0.28$ to 0.54) to muscle thickness as compared with height and BMI ($p < 0.001$). Weight and sex were able to account for 23-30% of the variance in muscle thickness values while they only accounted for 6% of the variance in endurance test times ($p < 0.003$). Combining all 4 endurance tests times, males were able to hold these positions about a minute longer than females ($p < 0.002$). However, there was no difference in trunk extensor endurance time between the sexes ($p > 0.20$). Relationship between endurance time with sex, height, BMI, and muscle thickness were low ($r < 0.20$).

Conclusion
Muscle thickness and symmetry values were consistent with findings of prior researchers. Sex and weight were significantly associated with muscle thickness, thus their possible confounding effects should be examined and their potential role as covariates considered in future research. Sex, height, weight, BMI, and muscle thickness values were poorly related to endurance hold times.

Clinical Relevance
Asymmetry of muscle thickness values was found in individuals without a history of LBP; its use as a clinical indicator or predictor for LBP requires further inquiry. Also, this study provides reference data for trunk muscle size and symmetry, which could be used for comparison studies for Soldiers with LBP.

Abstract #3 - Psychosocial Education Improves Low Back Pain Beliefs: Results from a Cluster Randomized Clinical Trial (NCT00373009)

Purpose
The general population has a pessimistic view of LBP and evidence based information has been used to positively influence LBP beliefs in previously reported mass media studies. Since previous studies utilized non-randomized methodologies, there is a lack of randomized trials demonstrating these effects in primary prevention settings. This cluster randomized clinical trial investigated the effect of a psychosocial educational program (PSEP) on low back pain (LBP) beliefs for Soldiers completing military training.

Subjects
Consecutive companies of Soldiers (n = 3,792) were recruited into this clinical trial.

Methods
Companies were cluster randomized to receive a PSEP or no education (CG). The PSEP consisted of an interactive seminar and Soldiers were issued the *Back Book* for reference material. LBP beliefs were assessed by the Back Beliefs Questionnaire (BBQ) before randomization and 12-weeks later. A linear mixed model was fitted for the BBQ change in continuous scale and a generalized linear mixed model was fitted for the dichotomous outcomes on BBQ change of greater than 2 points. Sensitivity analyses were performed to account for drop out.

Results
BBQ scores (potential range: 9 – 45) improved from baseline of 25.6±5.7 (mean±sd) to 26.9±6.2 for those receiving the PSEP, while there was a decline from 26.1±5.7 to 25.6±6.0 for those in the CG. These group differences were statistically significant ($p<0.0001$). The adjusted mean improvement for those receiving the PSEP was 1.74 points higher than those in the CG ($p<0.0001$). The adjusted odds ratio of BBQ improvement of greater than 2 points for those receiving the PSEP was 1.51 (95% CI = 1.22 – 1.86) times that of those in the CG. BBQ improvement was mildly associated with race, college education, and depression. Sensitivity analyses suggested minimal influence of drop out.

Conclusions
Soldiers that received the PSEP had an improvement in their beliefs related to the inevitable consequences of and ability to cope with LBP. The magnitude of improvement was clinically meaningful when compared to previous studies.

Clinical Relevance

Potentially maladaptive LBP beliefs can be positively altered by a group education program applied in a primary prevention setting.

In addition to the data from the abstracts, we also performed a longitudinal analysis related to mental health symptoms, and how they change over 12-weeks of training. We performed this analysis because predictors of mental health (primarily depression) and suicide in military populations have not received adequate research attention. Branches of the military need military-specific information about factors related to anxiety, depression, and suicide. Depression, anxiety, and suicidal ideation were examined at the beginning and end of the 12-week training. At the start of training, 10.4%, 15.5%, and 4.1% of soldiers had clinically significant depression, anxiety, or suicidal ideation, respectively. These percentages increased to 12.2%, 20.3%, and 5.7% at completion of training. Worsening of depression, anxiety, and suicidal ideation occurred for 7.7%, 11.4% and 4% of soldiers. At both the beginning and end of training, higher percentages of symptoms were associated with females, lower education, and lower income. Active duty personnel were more likely to worsen following training with respect to suicidal ideation (OR = 1.9, 95% CI: 1.2-2.9) compared to reservists.
This analysis represents one of the few prospective, pre-deployment investigations of depression, suicidal ideation, and anxiety in the military (Table 2).

Table 2. Results of Generalized Linear Mixed Models for the Dichotomous Outcomes on Depression, Anxiety, and Suicidal Ideation

Effects	Intake				Followup				Became Worse			
	Odds Ratio	95% CI		P-Value	Odds Ratio	95% CI		P-Value	Odds Ratio	95% CI		P-Value
Depression												
Age	0.94	0.91	0.97	0.0002	0.97	0.94	1.01	0.0943	0.99	0.96	1.03	0.7131
Gender – Female	1.73	1.39	2.16	<.0001	1.64	1.30	2.08	<.0001	1.62	1.22	2.15	0.0010
Race - Others	0.85	0.67	1.08	0.1810	0.83	0.64	1.08	0.1630	0.81	0.58	1.12	0.1947
Education - ≥ College	0.89	0.71	1.12	0.3275	0.79	0.62	1.01	0.0628	0.84	0.63	1.13	0.2585
Income - ≥ $35,000	0.87	0.63	1.18	0.3581	1.11	0.81	1.52	0.5066	1.40	0.98	2.00	0.0643
Time in Army – 1-3 yr	0.47	0.27	0.80	0.0058	1.45	0.77	2.73	0.2464	1.62	0.75	3.47	0.2170
Time in Army < 1 yr	0.52	0.35	0.77	0.0011	1.22	0.72	2.07	0.4604	1.32	0.70	2.52	0.3923
Navy/Air Force – No	0.56	0.32	0.97	0.0401	1.35	0.57	3.16	0.4951	1.96	0.60	6.34	0.2625
Active Duty - Yes	1.02	0.82	1.28	0.8529	1.26	0.99	1.61	0.0566	1.18	0.88	1.58	0.2712
Anxiety												
Age	0.94	0.91	0.97	<.0001	0.97	0.94	1.00	0.0183	0.99	0.96	1.02	0.6044
Gender – Female	1.39	1.15	1.68	0.0008	1.49	1.22	1.81	<.0001	1.36	1.06	1.74	0.0151
Race - Others	0.90	0.74	1.11	0.3252	0.83	0.67	1.02	0.0788	0.78	0.59	1.03	0.0763
Education - ≥ College	0.86	0.71	1.05	0.1347	0.80	0.66	0.98	0.0272	0.87	0.68	1.12	0.2750
Income - ≥ $35,000	0.96	0.74	1.24	0.7458	0.90	0.69	1.17	0.4354	1.00	0.72	1.38	0.9811
Time in Army – 1-3 yr	0.65	0.41	1.02	0.0610	0.84	0.50	1.41	0.5042	0.71	0.35	1.45	0.3447
Time in Army < 1 yr	0.60	0.42	0.85	0.0043	1.10	0.73	1.65	0.6428	1.34	0.79	2.27	0.2730
Navy/Air Force – No	0.85	0.50	1.45	0.5484	1.01	0.55	1.86	0.9806	0.87	0.43	1.79	0.7082
Active Duty - Yes	1.00	0.82	1.20	0.9573	1.22	1.00	1.48	0.0456	1.19	0.93	1.52	0.1584
Suicidal Ideation												
Age	0.97	0.92	1.02	0.1812	0.96	0.92	1.01	0.1263	0.97	0.92	1.03	0.3135
Gender – Female	1.13	0.80	1.61	0.4863	1.08	0.76	1.52	0.6828	1.06	0.70	1.60	0.7901
Race - Others	1.13	0.79	1.61	0.5040	1.12	0.79	1.60	0.5283	0.99	0.65	1.52	0.9662
Education - ≥ College	1.08	0.76	1.53	0.6736	1.06	0.76	1.50	0.7295	0.99	0.66	1.48	0.9660
Income - ≥ $35,000	0.70	0.42	1.16	0.1661	0.90	0.56	1.43	0.6396	1.14	0.68	1.92	0.6278
Time in Army – 1-3 yr	1.82	0.76	4.34	0.1775	2.71	0.96	7.64	0.0596	1.52	0.44	5.30	0.5125
Time in Army < 1 yr	1.10	0.52	2.32	0.8127	2.04	0.81	5.11	0.1307	1.89	0.67	5.31	0.2264
Navy/Air Force – No	1.03	0.37	2.88	0.9585	0.58	0.24	1.39	0.2236	0.65	0.23	1.87	0.4222
Active Duty - Yes	0.99	0.70	1.39	0.9567	1.57	1.11	2.22	0.0113	1.90	1.24	2.92	0.0034

In addition to Tasks specific to Year 3, the following recurring Tasks occurred:

Task 5: Complete quarterly procedures (Years 1 – 4)
(**NOTE: Task 5 will be completed once per quarter**)

- Conference call between all investigators
- Prepare quarterly reports
    - Manual of Operations
    - Monitor human subjects and safety monitoring

Task 6: Complete annual procedures (Years 1 – 4)
(**NOTE: Task 5 will be completed once per year**)

- On-site meeting between principal investigators
- Prepare annual reports
    - Manual of Operations
    - Human subjects and safety monitoring
- Renew institutional human subjects approval

Task 7: Prepare future proposals (Year 4)

- Conference call to discuss future DOD proposals related to prevention/treatment of musculoskeletal pain
    - Utilize established study infrastructure for data collection and management
    - Maintain established investigative team
- Preparation of subsequent DOD proposal related to prevention/treatment of musculoskeletal pain
- Submission of subsequent DOD proposal related to prevention/treatment of musculoskeletal pain

These activities were completed in Year 3, with details outlined below:

- Communication Between Investigators
    - Use of shared on-line calendar
    - Conference calls scheduled, as needed
- Investigator Meeting
    - Steven George and John Childs met in Las Vegas, NV to discuss long term follow up plans and plans for Year 4 (Deydre Teyhen was unavailable for the meeting due to her deployment).
- Institutional Review
    - BAMC human subject approval has been maintained continuously since February 2006, with appropriate modifications made as needed
    - University of Florida human subject approval has been maintained continuously since June 2006
    - USAMRMC HSRRB deferred review to BAMC June 2006
- Future proposal submitted
    - Proposal keeping research team intact was submitted for review to the PRMRP in 2008. This proposal focused on prevention of lower extremity pain
    - Received favorable review and score (1.6), but proposal was not awarded
    - Plan for resubmission in Year 4

KEY RESEARCH ACCOMPLISHMENTS

- 1 year follow up data summary indicates acceptable follow-up rates to test our hypotheses.

- Performance on the Army Physical Fitness Test (APFT) was not affected by performing the core stabilization exercise program (CSEP) utilized in this study. In fact, slightly higher passing rates were observed on the sit up portion of the APFT for Soldiers completing the CSEP.

- The psychosocial education program (PSEP) effectively improved Soldiers beliefs on the management of and ability to cope with low back pain (LBP). The size of improvement in LBP beliefs was comparable to other studies reported in Australia, Norway, and Scotland. This is the first time improvement in LBP beliefs has been reported from a clinical trial and also represents the first time these data have been reported from the United States.

- Worsening of depression, anxiety, and suicidal ideation occurred during advanced individual training (AIT) of combat medics. Specifically, sex, income, education, and reserve status were significant predictors of mental health status and these data may serve a practical purpose to aid in identification of individuals at risk for worsening mental health before deployment.

REPORTABLE OUTCOMES

Published abstracts

- George SZ, Teyhen DS, Wu SS, Wright A, Dugan JL, Yang G, Robinson ME, Childs JD. Psychosocial education improves low back pain beliefs: results from a cluster randomized clinical trial (NCT00373009). *J Orthop Sports Phys Ther,* abstracted 2009.

- Childs JD, George SZ, Wright A, Dugan JL, Benedict T, Bush J, Fortenberry A, Preston J, McQueen R, Teyhen DS. The effects of traditional sit-up training versus core stabilization exercises on sit-up performance in US Army soldiers: a cluster randomized trial (NCT00373009). *J Orthop Sports Phys Ther,* abstracted 2009.

- Teyhen, DS, Childs JD, Hall NM, Gervacio SC, Lopez JA, Mitchler JR, Wright A, Dugan JL, George SZ. The influence of sex, height, and weight on trunk muscle thickness and endurance. *J Orthop Sports Phys Ther,* abstracted 2009.

- George SZ, Childs JD, Teyhen DS, Wu SS, Wright AC, Dugan JL, and Robinson ME. Rationale, design, and protocol for the prevention of low back pain in the military (polm) trial (NCT00373009). *Proceedings of the 10th Annual Force Health Protection Conference*, abstracted 2007.

Papers in press

- George SZ, Teyhen DS, Wu SS, Wright AC, Dugan JL, Yang G, Robinson ME, Childs JD. Psychosocial education improves low back pain beliefs: results from a cluster randomized clinical trial (NCT00373009). *Eur Spine J*, in press.

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CONCLUSION

Overall

The POLM trial had another successful year. The research team was able to complete all Year 3 tasks in a timely fashion, and Year 4 tasks related to dissemination of early analyses and future proposals were also initiated. Recruitment has been completed, with over 4,000 Soldiers successfully enrolled in the trial. Follow-up assessment will continue in Year 4, with the continuation of our web-based survey, as well as continuation of our newly implemented telephone follow-ups and accessing health care utilization data.

So far, data from the trial provide encouraging preliminary results from the implemented exercise and education programs. These data have been disseminated through abstracts and manuscripts. First, it does not appear that performance of the core stabilization exercise program adversely affects performance on the Army Physical Fitness Test. Second, the education program implemented in the study effectively improved Soldier beliefs about low back pain. These findings bode well for our primary outcomes of incidence and severity of low back pain at 2 years.

So What?

The POLM trial is 1 year away from completion for its primary outcomes. Preliminary analyses have provided promising information on the exercise and education interventions used in the trial. We have also reported on risk factors of poor mental health, an important topic in the military. We will continue to monitor episodes of LBP over the next year so that the POLM trial can complete its planned 2 year follow up.

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APPENDICES

1. Copies of abstracts from 2009 Combined Sections Meeting
2. Proofs of *Military Medicine* article
3. Proofs of *European Spine Journal* article

mine the quality of published clinical prediction rules (CPRs) that have been developed for use in outpatient orthopaedic physical therapy settings. This review only included developmental phase CPRs for patients in outpatient settings with various orthopaedic conditions.
NUMBER OF SUBJECTS: This was a systematic review that included 10 studies.
MATERIALS/METHODS: A systematic review of the literature utilizing relevant databases (PubMed, CINAHL, ProQuest, Academic Search Premier) up to June 2008 resulted in the retrieval of 46 potential publications. Key words included "clinical prediction rule, predict, clinical, outcome and/or risk." Studies were included in this review if the explicit purpose of the study was to develop a CPR related to a specific treatment approach for orthopaedic conditions commonly treated by physical therapists. Previously validated CPRs were excluded from this review. Quality scores were independently assigned to each study by 2 reviewers utilizing a standard, previously published 18-item criteria list for assessing the methodological quality of prognostic studies.
RESULTS: Ten studies met criteria and were included in this review. Five studies involved CPRs for response to spinal manipulation. The other studies predicted response to lumbar stabilization, hip mobilization, patellar taping, multimodal treatment for cervical radiculopathy, and trigger point therapy for headache. Quality scores ranged from 10 to 15 (56%-83%) (mean, 11.80%, 65.70%), with a potential high score of 18 (100%).
CONCLUSIONS: Published CPRs for outpatient physical therapy varied in methodological quality. Studies commonly did not recruit inception cohorts, include adequately long follow-up times, or have large enough sample sizes. This review exemplifies the importance of considering methodological quality of CPR studies when validation studies are not available.
CLINICAL RELEVANCE: Physical therapists should consider the methodological quality of developmental phase studies involving CPRs prior to applying them into their clinical practice. This review also provides guidance for future CPR studies by highlighting need for recruitment of inception cohort, longer follow-up time, and larger sample sizes.

OPL13

THE IMMEDIATE EFFECTS OF UPPER THORACIC TRANSLATORIC SPINAL MANIPULATION (TSM) ON CERVICAL PAIN AND RANGE OF MOTION: A RANDOMIZED CLINICAL TRIAL

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PURPOSE/HYPOTHESIS: This study sought to determine if TSM would have an effect on cervical pain (measured by the FPS) and cervical ROM (measured by an inclinometer) when applied to hypomobile segments found in the upper thoracic region.
NUMBER OF SUBJECTS: 32.
MATERIALS/METHODS: Preintervention and postintervention active cervical rotation range of motion was measured with a cervical inclinometer (CROM), and cervical pain status was monitored before and after manipulation with a Faces Pain Scale. A convenience sample of 32 patients referred to physical therapy with complaints of pain in the mid-cervical region and restricted active cervical rotation participated in the study. Twenty-two patients were randomly assigned to the experimental group and 10 were assigned to the control group. Preintervention and postintervention cervical range of motion and pain scale measurements were taken by a physical therapist assistant who was blinded to group assignment. The experimental group received TSM to hypomobile upper thoracic segments. The control group received no intervention. Paired *t* tests were used to analyze within group changes in cervical rotation and pain and a 2-way repeated-measure ANOVA was used to analyze between group differences in cervical rotation and pain. Significance was accepted at the $P = .05$.
RESULTS: Significant changes which exceed the MCD95 were detected for cervical rotation both within group and between groups with the TSM group demonstrating increased mean (SD) in right rotation of 8.23° (7.41°) and left rotation 7.09° (5.83°). Pain levels perceived during postintervention cervical rotation showed significant improvement during right rotation for patients experiencing pain during bilateral rotation only ($P = .05$).
CONCLUSIONS: This study supports the hypothesis that spinal manipulation applied to the upper thoracic spine (T1-T4 motion segments) significantly increases cervical rotation ROM and may reduce cervical pain at end range rotation for patients experiencing pain during bilateral cervical rotation.
CLINICAL RELEVANCE: This study adds to the growing body of evidence supporting the use of spinal manipulation in clinical practice. This study also identifies some of the limitations of thoracic manipulation in addressing neck pain.

OPL14

THE EFFECTS OF TRADITIONAL SIT-UP TRAINING VERSUS CORE STABILIZATION EXERCISES ON SIT-UP PERFORMANCE IN US ARMY SOLDIERS: A CLUSTER RANDOMIZED TRIAL (NCT00373009)

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PURPOSE/HYPOTHESIS: Despite the tradition of performing sit-ups in the US Army, it has been postulated that this exercise increases lumbar spine loading, potentially increasing the risk of injury and low back pain (LBP). Therefore, health professionals commonly recommend "core stabilization" exercises, which may improve abdominal and trunk muscle strength without excessive spine loading, thus potentially decreasing the incidence of LBP. However, core stabilization exercise programs (CSEP) have not been widely adopted in the US Army because of the perceived deleterious impact on sit-up performance on the Army Physical Fitness Test (APFT). Therefore, the purpose of this study was to determine whether performing CSEP in lieu of traditional sit-ups has detrimental effects on APFT sit-up performance and pass rates.
NUMBER OF SUBJECTS: 2616.
MATERIALS/METHODS: Subjects included healthy Soldiers between 18 and 35 years of age participating in Advanced Individual Training. Soldiers with a previous history of LBP were excluded. Companies of Soldiers were cluster randomized to receive traditional exercise program (TEP) or CSEP. TEP consisted of exercises that target the rectus abdominus, oblique abdominals, and hip flexor musculature. CSEP was comprised of exercises that target the transversus abdominus and multifidi musculature. Soldiers completed their exercise program during unit physical training 4 times per week for 12 weeks. Performance on the AFPT was assessed at baseline and 12 weeks. Descriptive statistics were calculated to summarize the data. Independent variables were Group, Quartile, and Time. Dependent measures were scores and pass rates for sit-up, push-up, and overall APFT. A $2 \times 4 \times 2$ repeated-measures ANOVA with pairwise comparisons using the Bonferroni inequality was used to examine differences in the overall and sit-up scores. Differences in pass rates were assessed with a chi-square. The alpha-level was set to .05 a priori.
RESULTS: The mean age of subjects was 21.9 ± 4.3 years of age. Both groups performed sit-ups outside of unit physical training at equal rates (TEP, 69.5%; CSEP, 65%; $P = .067$). Both groups significantly improved their overall and sit-up score and pass rates over time ($P<.05$). There were no significant between group differences in overall scores ($P = .142$) or sit-up performance ($P = .543$) on the APFT after 12 weeks of training. CSEP and TEP improved their sit-up pass rates by 5.6% and 3.9%, respectively ($P<.05$). The NNT for CSEP was 55.6 (95% CI: 55.5, 55.6).

CONCLUSIONS: CSEP did not have a detrimental impact on APFT scores or pass rates. There was actually a small but significantly greater increase in sit-up pass rate in the CSEP (5.6%) versus the TEP (3.9%). Therefore, incorporating CSEP into Army physical training does not increase the risk of suboptimal performance on the APFT.
CLINICAL RELEVANCE: A company with 400 Soldiers performing CSEP would potentially result in 7 additional Soldiers progressing from a failure to a pass on the sit-up component of the APFT compared to TEP.

OPL15

DIAGNOSIS OF SERIOUS SPINAL PATHOLOGY IN PATIENTS PRESENTING TO PRIMARY CARE WITH ACUTE LOW BACK PAIN

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PURPOSE/HYPOTHESIS: We aimed to determine the proportion of people presenting to primary care practitioners with low back pain caused by previously undiagnosed serious pathology and the diagnostic accuracy of a variety of red flag questions singly and in combination.
NUMBER OF SUBJECTS: 1172.
MATERIALS/METHODS: We recruited an inception cohort of 1172 consecutive patients attending primary care (physiotherapists, general practitioners, chiropractors) for acute low back pain. At the initial consultation clinicians recorded responses to 25 red flag questions and then provided an initial diagnosis. The reference standard was a 12-month follow-up supplemented with a specialist review of a random subsample of participants.
RESULTS: There were 11 cases (0.9%) of serious pathology including 8 fractures. Despite the low prevalence of serious pathology, most patients (80.4%) had at least 1 red flag (median 2, IQR 1-3). Clinicians identified 5 of the 11 cases of serious pathology at the initial consultation, and made 6 false-positive diagnoses (LR+ = 88, LR− = 0.55). Status on a diagnostic prediction rule containing 4 red flags: female gender, age greater than 70 years, significant trauma and prolonged use of corticosteroids was moderately associated with the presence of fracture (χ^2 = 30.4, P<.000, r^2 = 0.326). It was not possible to evaluate red flags for conditions other than fracture because of the low prevalence of these other conditions.
CONCLUSIONS: In people presenting to primary care with back pain, previously undiagnosed serious pathology is rarely the cause. The most common serious pathology is vertebral fracture. About half of the cases of serious pathology are identified at the initial consultation. Most individual red flags are of little use, but a diagnostic prediction rule comprising 4 red flags can be used to screen for fracture.
CLINICAL RELEVANCE: Screening for undiagnosed serious pathology is an important part of contemporary physical therapy practice. Our study has developed a simple tool that clinicians can use to screen for undiagnosed fracture in their patients with acute low back pain.

OPL16

THE EFFECT OF A WORKSHOP ON USING SPECIFIC EXERCISES ON THE OUTCOMES OF PATIENTS WITH LOW BACK PAIN AND TREATMENT-BASED CLASSIFICATION

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PURPOSE/HYPOTHESIS: The goal was to determine the effect on patient's outcomes and physical therapist's (PT) classification behaviors of a training workshop about the specific exercise category of the treatment-based classification (TBC) system. We hypothesized that training would improve the outcomes of patients in this category.
NUMBER OF SUBJECTS: The outcome of patient with low back pain (LBP) with at least 2 visits between 2004 and 2007 (n = 5109) were retrospectively extracted from a database. Only PTs treating at least 30% of their caseload for LBP and familiar with the TBC for LBP were selected.
MATERIALS/METHODS: Nineteen PTs volunteered for the workshop. Training consisted of a 21-hour workshop with patient demonstrations, case studies and lectures on the assessment and treatment of patients with LBP using specific exercises. The workshop instructor had 10-plus years of teaching, clinical and research experience. Data on patient's outcomes averaged for each 3-month period from PTs who participated in the workshop were compared to 14 PTs who did not participate using run-charts (P-chart and Xbar/S) with 95% confidence intervals. We compared PT groups for the proportion of patients classified, days in therapy, number of visits, disability and pain levels in each category of the TBC system.
RESULTS: There were no differences between groups of PTs in experience using specific exercises or in ranking for which treatment category they had most expertise or hours of training. The proportion of patients classified in the specific exercise category did not differ between participants and nonparticipants before and after the workshop and did not change after the workshop. Days spent in therapy, number of visits, the Oswestry disability and pain outcomes did not differ between groups of PTs either before or after the workshop. Outcomes did not change from before to after the workshop in both groups. In both groups, from just before to after the workshop, the proportion of patients classified in specific exercises did not change (χ^2, P<.05). Repeated-measures ANOVAs for the specific exercise category showed no differences between groups or from before to after the workshop in disability and pain relief. Workshop participants used less visits overall. Both PT groups had shorter therapy durations and less visits after the workshop. Control charts for all trimesters and ANOVAS comparing trimesters before and after the workshop showed that the workshop did not have any adverse effects on the proportion of patients classified, or the outcomes of the patients in the other TBC treatment categories.
CONCLUSIONS: No significant effects on patient's outcomes were observed following participation in a workshop on the assessment and treatment of patients in the specific exercise category of the TBC system. No adverse effects were observed in primary or balance measures.
CLINICAL RELEVANCE: Results are consistent with the literature on passive continuing medical education strategies. The effect of active training strategies should be examined.

OPL17

PATIENT CLASSIFICATION BASED ON PSYCHOSOCIAL VARIABLES PREDICTS TREATMENT OUTCOMES IN PATIENTS WITH LOWER BACK PAIN WHO MEET A CLINICAL PREDICTION RULE

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PURPOSE/HYPOTHESIS: Self-efficacy (SE), activity-related fear, and pain are interrelated concepts that are significant individual predictors of disability in patients with lower back pain (LBP). Identification of patient subgroups involving these variables will refine our understanding of how they interact to affect treatment outcomes. The purpose of this study was to preliminarily validate a classification system for patients with post-acute LBP based on SE, fear, and pain.
NUMBER OF SUBJECTS: Subjects with LBP and related lower extremity pain (n = 111) who met criteria of a clinical prediction rule that identifies a high probability of optimal clinical outcome related to lumbopelvic ma-

nipulation were enrolled into an existing randomized clinical trial.
MATERIALS/METHODS: Subjects completed measures of SE (Lower Back Activity Confidence Scale function [LoBACS-FN], self-regulation [LoBACS-SR], and exercise [LoBACS-EX] subscales), activity-related fear (Fear Avoidance Beliefs Questionnaire physical activity [FABQ-PA] and work [FABQW] subscales), disability (Oswestry Disability Index [ODI]) and average pain (Numeric Pain Rating Scale [NPRS]) at intake. Subjects completed these measures and the Global Rating of Change (GROC) scale at 1 week, 4 weeks and 6 months following intake. Optimal cluster number for standardized LoBACS subscale, FABQ subscale, and NPRS scores at intake was determined by hierarchical cluster analysis. Cluster membership for each subject then was established by nonhierarchical cluster analysis. Guttman's split half reliability estimate (λ) was calculated for the resulting model. Analysis of variance (ANOVA) and Kruskal Wallis tests were used to compare ODI and GROC, respectively, among clusters.
RESULTS: A 4-cluster solution was identified, including low fear and SE (n = 22); high FABQW and pain-low LoBACS-FN (n = 10); high FABQPA-low LoBACS-SR (n = 44); and low fear and pain-high SE (n = 35) groups. ANOVA revealed significant differences in all cluster variables across clusters at intake ($P<.05$). Guttman's λ was .635, indicating fair reliability. ODI score was significantly different across groups at intake ($P<.01$) and 6 months ($P<.05$). Significantly worse GROC at 6 months was reported in the high FABQW and pain-low LoBACS-FN group at 6 months ($P<.05$). Magnitude of change in NPRS score significantly differed across groups at all time points ($P<.01$). LoBACS subscale scores significantly differed across groups at 4 weeks ($P<.001$), while FABQW remained significantly elevated in the high FABQW and pain-low LoBACS-FN group at 4 weeks and 6 months ($P<.01$).
CONCLUSIONS: This study's findings indicate patients may be classified into valid and reliable subgroups by psychosocial characteristics, which demonstrate significant differences in outcomes. Future studies should validate this approach in the broader population of patients with LBP.
CLINICAL RELEVANCE: This study provides a preliminary framework for physical therapists to integrate information regarding SE, fear, and pain into clinical management plans for patients with LBP.

OPL18

FACTORS ASSOCIATED WITH UTILIZING MOBILIZATION AND MANIPULATION TECHNIQUES BY PHYSICAL THERAPISTS IN THE OUTPATIENT SETTING

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PURPOSE/HYPOTHESIS: Low back pain is 1 of the most common problems encountered by outpatient physical therapists. It accounts for more than one quarter of outpatient physical therapy referrals and almost one half of outpatient physical therapy visits. Spinal manipulation is an effective treatment for low back pain, to reduce pain and disability, and to increase joint mobility. However, it is grossly underutilized by physical therapists. The purpose of this study was to identify the use of manipulation by licensed physical therapists and physical therapy students, as well as factors influencing its utilization.
NUMBER OF SUBJECTS: 210 questionnaires were mailed to clinical instructors in the outpatient setting who were affiliated with, or previously affiliated with an academic physical therapy program.
MATERIALS/METHODS: The survey instrument was developed and validated by physical therapy students and faculty from an academic physical therapy program. The final construct contained 34 items. Survey items included demographics, education on manipulation techniques and the use of and comfort level with performing and instructing nonthrust and thrust manipulation techniques by physical therapists and the physical therapy students they supervise.
RESULTS: The response rate was 79 (37.6%). A significantly greater number of subjects reported use of nonthrust versus thrust techniques (79.7% and 30.4%, respectively; $P<.001$). These percentages are not all-inclusive, as some subjects who use thrust techniques also use nonthrust techniques. Respondents who incorporated nonthrust and thrust techniques into their plans of care were more likely to be members of the APTA and/or the orthopedic section of the APTA, be members of the AAOMPT, to have received certification in manual therapy, and/or to have received education in manipulation techniques in their entry level education or through continuing education.
CONCLUSIONS: Professional involvement and manipulation training through entry level or continuing education appear to positively influence physical therapists' comfort with and use of nonthrust and thrust techniques in the outpatient orthopedic setting.
CLINICAL RELEVANCE: In order to expand the appropriate use of manipulation techniques in physical therapy practice, entry level physical therapy education programs should include manipulation as an expected competency and model professional involvement and commitment to lifelong learning.

OPL19

THE INFLUENCE OF SEX, HEIGHT, AND WEIGHT ON TRUNK MUSCLE THICKNESS AND ENDURANCE

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PURPOSE/HYPOTHESIS: Trunk muscle endurance may have an important role in the prevention and treatment of low back pain (LBP). Direct assessment of trunk muscle function is not feasible. Therefore, muscle morphometry has been used as an indirect measure. The purpose was to describe how sex, height, weight, and body mass index (BMI) influence trunk muscle thickness and endurance times and to provide reference data for trunk morphometry in Soldiers.
NUMBER OF SUBJECTS: Soldiers (144 males, 46 females; 21.6 $\pm$ 4.0 years; 24.7 $\pm$ 2.9 kg/m^2) attending combat medic training without a history of LBP were enrolled.
MATERIALS/METHODS: Ultrasound images were obtained bilaterally at rest for the following trunk muscles: rectus abdominis, transversus abdominis (TrA), internal oblique, and external oblique, and lumbar multifidus at L4-L5. The following 4 endurance tests were assessed: supine flexor endurance test, prone extensor endurance test, and right and left horizontal side support. Independent t tests were performed to determine if muscle thickness, muscle symmetry, or endurance times differed based on sex. Pearson product moment correlations were performed to determine the associations between height, weight, and BMI with muscle thickness values. Sex and weight were included in regression analysis to determine their contribution to the variance in trunk muscle thickness. Finally, sex, weight, and muscle thickness values were included in a regression analysis to determine their contribution to the variance in endurance times.
RESULTS: Muscle thickness was greater in males than females ($P<.006$). However, the TrA accounted for 10% of total abdominal muscle thickness regardless of sex. Muscle symmetry ranged from 6.6% to 19.8% but did not differ based on sex ($P>.34$). Asymmetry was greater than 12% for the lateral abdominal muscles. Weight had a stronger correlation (r = 0.28 to 0.54) to muscle thickness as compared with height and BMI ($P<.001$). Weight and sex were able to account for 23% to 30% of the variance in muscle thickness values while they only accounted for 6% of the variance in endurance test times. Males were able to hold the 4 endurance test postures about a minute longer than females ($P<.002$). However, there was no difference in trunk extensor endurance time between the sexes ($P>.20$). Relationship between endurance time with sex, height, BMI, and muscle thickness were low ($r<0.20$).
CONCLUSIONS: Muscle thickness and symmetry values were consistent

with findings of prior researchers. Sex and weight were significantly associated with muscle thickness, thus their possible confounding effects should be examined and their potential role as covariates considered in future research. Sex, height, weight, BMI, and muscle thickness values were poorly related to endurance hold times.
CLINICAL RELEVANCE: Asymmetry of muscle thickness values was found in individuals without a history of LBP; its use as a clinical indicator or predictor for LBP requires further inquiry. This study also provides normative data for trunk muscle size and symmetry, which could be used for comparison studies in a similar population with LBP.

OPL20

MOTOR CONTROL EXERCISE FOR PERSISTENT NONSPECIFIC LOW BACK PAIN: A SYSTEMATIC REVIEW

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PURPOSE/HYPOTHESIS: Previous systematic reviews investigating the role of motor control exercise in the treatment of persistent nonspecific low back pain have reached no clear conclusion. A number of studies evaluating motor control exercise have recently been conducted and therefore a new systematic review may enable better estimation of the effectiveness of this treatment. The aim of this study was to perform a systematic review, using a meta-analytical approach, to evaluate the effect of motor control exercise in patients with subacute, chronic and recurrent nonspecific low back pain.
NUMBER OF SUBJECTS: Eleven trials were included in the review.
MATERIALS/METHODS: Relevant electronic databases were searched up to October 2007. Two independent reviewers extracted data and rated trial quality. Based on statistical heterogeneity trials were pooled using either a fixed or a random effects model. Treatment effects were presented as weighted mean differences (WMD).
RESULTS: Eleven trials were included in the review, with 7 of these, comparing motor control exercise to minimal intervention, sufficiently similar to enable pooling. The pooling revealed that motor control exercise was effective in reducing pain at short (WMD on a 0-100 scale of −14.27 points; 95% CI: −20.45, −8.08), intermediate (−13.76 points; 95% CI: −22.55, −4.88) and long-term follow-up (−14.39 points; 95% CI: −23.11, −5.67). Pooled results comparing motor control exercise to spinal manipulative therapy and to other forms of exercise showed no difference in the effect on pain.
CONCLUSIONS: These results suggest that while motor control exercise appears better than a minimal intervention in reducing pain in the short, intermediate and long-term, motor control exercise appears no more effective than spinal manipulative therapy or other forms of exercise in reducing pain in patients with persistent, nonspecific low back pain.
CLINICAL RELEVANCE: When treating patients with persistent non specific low back pain the lack of difference in effect between commonly used physiotherapy treatments such as exercise, spinal manipulative therapy and motor control exercise, suggests that patient preferences and therapist expertise should firstly be considered when determining which treatment to use.

OPL21

COMPARISON OF 2 SUBGROUPS OF PATIENTS WITH CHRONIC LOW BACK PAIN CLASSIFIED WITH THE MOVEMENT SYSTEM IMPAIRMENT CLASSIFICATION SYSTEM

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PURPOSE/HYPOTHESIS: Classification of patients with low back pain (LBP) into subgroups may assist in determining the most effective treatment and predicting prognosis. A standardized examination based on the Movement System Impairment (MSI) model has been proposed to classify people with LBP. The examination includes tests of signs related to mechanical factors and symptoms. Our purpose was to test for differences in baseline characteristics of subgroups of people classified based on the MSI clinical examination. We tested for differences in the 2 most prevalent subgroups; patients in the Rotation (Rot) subgroup and patients in the Rotation-Extension (RotExt) subgroup. We hypothesized that patients classified in the Rot subgroup would report greater functional limitations than patients classified in the RotExt subgroup and there would be no differences between the groups in other variables.
NUMBER OF SUBJECTS: The sample included 57 subjects (mean age, 42.2 ± 11.4 years; 30 female, 27 male) with chronic LBP enrolled in a randomized clinical trial comparing 2 different treatments for LBP.
MATERIALS/METHODS: Subjects were classified based on findings from the MSI standardized examination (Rot, n = 35 and RotExt, n = 22). We compared the 2 groups on variables related to (1) demographics, (2) LBP history, (3) general health, (4) activity level, (5) function and (6) symptoms. Independent samples *t* test and the chi-square test were used to test for differences between the groups.
RESULTS: The 2 LBP groups were similar in height, weight, LBP history, 6/8 SF-36 subscale scores, activity level, fear avoidance and numerical pain score (current, average and worst). Subjects classified into the Rot subgroup displayed higher scores on the Modified Oswestry (M = 22.8 ± 9.1) than the RotExt subgroup (M = 17.7 ± 7.5; t[54] = 2.177; $P = .034$). The Rot subgroup also scored lower on the SF-36 Physical Function subscale score (M = 73.3 ± 16.4) than the RotExt subgroup (M = 83.4 ± 11.7; t (55) = −2.493; $P = .016$). The Rot subgroup scored lower on the SF-36 Bodily Pain subscale score (M = 55.7 ± 13.6) than the RotExt subgroup (M = 63.2 ± 13.0; t (55) = −2.069; $P = .043$).
CONCLUSIONS: In this sample the Rot subgroup reported significantly greater functional limitations than the RotExt subgroup. The groups were similar in other baseline characteristics, in particular LBP symptoms. Thus, differences in the 3 functional variables were likely not a result of differences in LBP severity between the groups.
CLINICAL RELEVANCE: These findings are important because they support the proposal that LBP groups differ in predictable ways, providing additional evidence that the groups are distinct. These findings also suggest that the LBP subgroups may differ in the mechanical factors that contribute to differences in the extent of functional limitations and disability. These mechanical factors may also impact prognosis. Funded by NIH R01 HD047709.

OPL22

IMPACT LOADS AND PLANTAR STRESSES WHILE WALKING IN SUBJECTS WITH ADULT-ACQUIRED, NEUROPATHIC MEDIAL COLUMN FOOT DEFORMITY

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PURPOSE/HYPOTHESIS: Adult-acquired, rigid neuropathic foot deformities place the individual at high-risk for ulceration and lower extremity amputation.
PURPOSE: To report the impact loads and plantar stresses during barefoot walking in subjects with diabetes mellitus (DM), peripheral neuropathy (PN) and a unilateral acquired, rigid neuropathic deformity of the medial column of the foot compared to age-, sex- and race-matched control subjects without rigid deformity.
NUMBER OF SUBJECTS: Fifteen subjects (17 feet; 9 men, 6 women; mean age, 55 ± 11 years) with chronic DM, PN and a rigid, nonreducible neuropathic deformity of the medial column of the foot were studied. Thirty subjects (15 men, 15 women) that were age-, sex- and race-matched served as controls.
MATERIALS/METHODS: All subjects walked barefoot at their preferred walking speed over an Emed-ST pressure platform (Novel Inc, St Paul MN) using a 2-step approach. Subjects walked 2-3 trials for each foot.
ANALYSIS: Each step yielded a plantar map that was divided into 3 masks

Mental Health Symptoms in Combat Medic Training: A Longitudinal Examination

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ABSTRACT Mental health symptoms in military populations are rising and constitute a significant health concern. This study examined the prevalence of depression, anxiety, and suicidal ideation in soldiers (N = 3,792) undergoing combat medic training. At the start of training, 10.4%, 15.5%, and 4.1% of soldiers had clinically significant depression, anxiety, or suicidal ideation, respectfully. These percentages increased to 12.2%, 20.3%, and 5.7% at completion of training, respectfully. Worsening of depression, anxiety, and suicidal ideation occurred for 7.7%, 11.4%, and 4% of soldiers. Higher percentages of symptoms were associated with females, lower education, and lower income. Active duty personnel were more likely to worsen following training with respect to suicidal ideation (OR = 1.9, 95% CI = 1.2–2.9) compared to reservists. The identification of these significant predictors of mental health status may serve to identify individuals at risk. Additional work to examine the relative contribution of anticipatory (impending deployment) factors vs. training-related factors is warranted.

INTRODUCTION

Recent reports[1–3] have highlighted the concern over depression and suicide in military populations. In addition to the scientific literature, reports about mental health issues in the military have become frequent in the popular press.[4] Moderate or greater depression has been reported in 15.9% of entry level military personnel.[1] Both male (15%) and female (22%) personnel reported depressive symptomatology. A recent study by the Rand corporation[4] indicated that approximately 18.5% of U.S. service members returning from current conflicts in Iraq and Afghanistan suffered from depression or post-traumatic stress disorder. Thus, both scientific literature and popular media accounts suggest a large number of U.S. military personnel involved in current conflicts report significant mental health problems.

Related to the above-mentioned depression rates are reports that military personnel have significant rates of suicidal ideation.[2,5,6] Army reports[6] indicate a significant increase in suicides since recording began in 2002. There were 350 reported suicides in 2002, and 2,100 reported in 2007. This same report indicated that the majority of suicides occurred stateside and included both formerly deployed and those who had not been deployed.

Predictors of mental health (primarily depression) and suicide in military populations have not received adequate research attention.[2] Although similar to predictors in the civilian population,[7] Allen and colleagues[2] noted that the branches of the military need additional military-specific information about factors related to suicide. They suggested that viable candidate factors included deployment status, combat stress, alcoholism, and sex/gender.

The purpose of this study was to examine mental health symptoms (depression, suicidal ideation, and anxiety) in a sample of soldiers enrolled in combat medic training. The data were collected as part of a longitudinal study examining back pain in the military and offered a relatively unique opportunity to examine the aforementioned mental health symptoms in a longitudinal design.[8] This design allowed us to describe incidence of these symptoms, and change in mood, and suicidal ideation as soldiers completed training and faced potential deployment to combat situations. Finally, we were interested in examining predictor variables of both baseline mental health symptoms and changes in mental health status with training. Specifically, we tested the hypothesis that female soldiers would have higher levels of depression, anxiety, and suicidal ideation and would be more likely to transition from subclinical to clinical levels of depression, anxiety, and suicidal ideation than male soldiers. Military status (active vs. reserve) was also expected to predict mental health status, with reservists less likely to have mental health symptoms than active duty soldiers. Other exploratory analyses examined age of soldier, previous military experience, education, and income as predictors of baseline mental health symptoms and changes with training.

MATERIALS AND METHODS

Study sample

Participants were composed of the first 18 companies of soldiers (n = 3,792) who participated in the randomized clinical

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trial on prevention of low back pain in the military (POLM).[8] These soldiers entered the combat medic 12-week Advanced Individual Training (AIT) program at Fort Sam Houston, Texas. Research staff at Fort Sam Houston, Texas introduced the study to individual companies of soldiers. Soldiers were screened for eligibility, and informed consent was obtained, as appropriate. For 12 consecutive months soldiers were screened for eligibility according to the following inclusion/exclusion criteria.

Inclusion criteria

- Ages 18 (or emancipated minor that is 17 years old) to 35 years old.
- Participating in combat medic military occupational specialty (MOS) training.
- English speaking and reading.

Exclusion criteria

- Prior history of low back pain (LBP) (operationally defined as LBP that limited work or physical activity, lasted longer than 48 hours, and caused the subject to seek health care) or previous medical history for any prior surgery for LBP.
- Currently seeking medical care for LBP.
- History of degenerative joint disease, arthritis, spine trauma or vertebral fractures, and/or spondylolisthesis.
- Currently unable to participate in physical fitness training due to injury in foot, ankle, knee, hip, neck, shoulder, elbow, wrist, or hand.
- History of fracture (stress or traumatic) in proximal femur and/or pelvis.
- Currently pregnant.
- Previous failure of AIT.

Dependent variables

The dependent variables for the study included depression, anxiety, and suicidal ideation. Their measurement is described below.

1. The Beck Depression Inventory (BDI), a 21-question multiple-choice self-report inventory, was used to measure the severity of depression. A total score for the BDI is calculated by summing the score for each item. Scores can range from 0 to 63. Soldiers who scored 15 or higher were classified as clinically depressed.
2. Soldiers who chose answers 1–3 for Question 9 of the BDI were designated as having suicidal ideation. Conversely, those who chose answer 0 were designated as not suicidal.
3. For anxiety, State Trait Anxiety Inventory (STAI) form Y-2 was used. The STAI yields summary scores ranging from 0 to 80. A total score of 46 or above was classified as clinically significant anxiety.

All three dependent variables were measured two times: at intake and at 12-week follow-up. A soldier was designated "worsened" if (s)he changed from not depressed to depressed and similarly for changing from subclinical anxiety to clinically significant anxiety and changing from not suicidal to suicidal ideation. Individuals who endorsed suicidal ideation were immediately referred with an accompanying soldier to base mental health services for a more complete evaluation. Data from these encounters were not available to the study personnel.

Independent variables

This study investigated three military related factors: (1) how long a soldier has been enlisted in the Army (time in Army: <1 year, 1–3 years, >3 years), (2) whether a soldier has previously been in the Navy (including Marines) or the Air Force (Navy or Air Force: yes, no), and (3) whether a soldier is a full-time active duty service member (active duty: yes, no).

Sociodemographic variables

Variables of interest and for risk adjustment in our final models included age (continuous), gender (female, male), race (white or Caucasian, others), highest level of education (education: college or more, high school or less), and approximate household income (income: $35,000 or more, less than $35,000).

Statistical analysis

All data were analyzed using SAS version 9.1. First, descriptive statistics were obtained on the sociodemographic and clinical variables. Second, generalized linear mixed models were fitted for the dichotomous outcomes on depression, anxiety, and suicidal ideation, including a random effect of company for the dependency of soldiers within the same unit and adjusting for the sociodemographic factors discussed above. In addition, we have fitted linear mixed models for the continuous depression and anxiety scores to estimate the effects of independent variables. The level of statistical significance was set at 0.05.

RESULTS

Among the 3,792 soldiers enrolled in the POLM study in the first three rounds, 72% were white or Caucasian, 71% were male, 53% had college or more education, 18% had $35,000 or more household income, 84% had been enlisted in the Army for less than 1 year and 9% for 1–3 years, 3% had previously been in the Navy (Marines) or the Air Force, and 59% were full-time active duty service members (Table I). The study population had a mean age of 22 years (SD = 4.39). Distributions of these variables were nearly the same for the 2,931 soldiers who remained at 12-week follow-up, suggesting limited potential of bias from soldiers who did not complete the follow-up assessment. T1

Table II showed that, at time of intake, 10.39%, 15.51%, and 4.11% of soldiers had depression, anxiety, and suicidal T2

ideation, respectively; and these percentages increased to 12.18%, 20.31%, and 5.70% at time of follow-up. In addition, 7.71%, 11.36%, and 3.99% of soldiers worsened in the three outcomes, respectively. Table II also showed that soldiers who are female, with high school or less education or with less than $35,000 income, had higher percentages of symptoms at both times of intake and of follow-up.

Table III presents the results of generalized linear mixed models for the dichotomous outcomes on depression, anxiety, and suicidal ideation. Compared with soldiers enlisted more than 3 years in the Army, the odds of having depression at time of intake were 0.47 times for those enlisted 1–3 years; similarly the odds of having depression and anxiety at time of intake were 0.52 and 0.60 times for those enlisted less than 1 year. Also, those who had not previously been in the Navy (Marines) or the Air Force had 0.56 times odds of having depression at the time of intake compared to their counterparts. These differences were not significant at the time of follow-up. In addition, the full-time active duty service members had 1.22 times and 1.57 times odds of anxiety and suicidal ideation at time of follow-up and 1.90 times odds of becoming worse in suicidal ideation, compared to those from a Reserve or National Guard unit. T3

Our results also show that female soldiers had significantly higher risk in the outcomes. More specifically, the odds of having depression at intake, depression at follow-up, or worsening depression for female soldiers were 1.73, 1.64, and 1.62 times compared to males; similarly the odds ratios of having anxiety at intake, anxiety at follow up, or worsening anxiety were 1.39, 1.49, and 1.36, respectively. Other factors significantly related to the outcomes were that older age was associated with lower odds of depression and anxiety and college or more education was associated with lower odds of anxiety at time of follow-up.

TABLE I. Sociodemographic and Military Characteristics of the Study Sample

	Intake		Follow-up	
Factors	*n*	%	*n*	%
Race				
Other		28	757	26
Caucasian	2,743	72	2,174	74
Gender				
Female	1,103	29	849	29
Male	2,689	71	2,082	71
Education				
College or higher	2,028	53	1,631	56
High school or lower	1,764	47	1,300	44
Income				
≥$35,000	665	18	521	18
≤$35,000	3,118	82	2,404	82
Time in Army				
1–3 years	322	9	268	9
<1 year	3,199	84	2,458	84
>3 years	269	7	203	7
Navy/Air Force				
No	3,668	97	2,849	97
Yes	124	3	82	3
Active Duty				
Yes	2,254	59	1,688	58
No	1,538	41	1,243	42
Age (mean [SD])	21.98	4.39	22.00	4.38
Total	3,792	100	2,931	100

TABLE II. Percentages of Soldiers Who Had Depression (*D*%), Anxiety (*A*%), and Suicide Attempt (*S*%)

	Intake				Follow-up				Became Worse			
Factors	*n*	*D*%	*A*%	*S*%	*n*	*D*%	*A*%	*S*%	*n*	*D*%	*A*%	*S*%
Race												
Other	1,049	9.53	14.68	4.48	757	10.96	18.40	6.08	757	6.87	9.86	3.96
Caucasian	2,743	10.72	15.82	3.97	2,174	12.60	20.97	5.57	2,174	8.00	11.89	4.00
Gender												
Female	1,103	14.05	18.59	4.62	849	15.90	24.56	6.01	849	10.25	13.40	4.12
Male	2,689	8.89	14.24	3.90	2,082	10.66	18.57	5.57	2,082	6.68	10.53	3.94
Education												
College or higher	2,028	9.42	13.61	3.94	1631	10.73	18.02	5.46	1,631	7.17	10.69	3.80
High school or lower	1,764	11.51	17.69	4.31	1300	14.00	23.18	6.00	1,300	8.38	12.20	4.23
Income												
≥$35,000	665	8.57	13.53	2.86	521	11.71	17.05	4.80	521	9.21	10.73	4.03
≤$35,000	3,118	10.81	15.97	4.39	2,404	12.31	21.02	5.91	2,404	7.40	11.48	3.99
Time in Army												
1–3 years	322	10.25	18.01	6.52	268	14.55	17.16	6.72	268	9.33	6.72	2.99
<1 year	3,199	10.16	15.04	3.94	2,458	12.25	20.97	5.86	2,458	7.73	12.12	4.27
>3 years	269	13.38	17.84	3.35	203	8.37	16.18	2.46	203	5.42	8.33	1.97
Navy/Air Force												
No	3,668	10.31	15.57	4.14	2,849	12.32	20.44	5.65	2,849	7.83	11.38	3.97
Yes	124	12.90	13.71	3.23	82	7.32	15.66	7.32	82	3.66	10.84	4.88
Active duty												
Yes	2,254	10.29	15.17	3.99	1,688	12.86	21.72	6.58	1,688	7.94	12.34	4.98
No	1,538	10.53	15.99	4.29	1,243	11.26	18.38	4.51	1,243	7.40	10.03	2.65
Total	3,792	10.39	15.51	4.11	2,931	12.18	20.31	5.70	2,931	7.71	11.36	3.99

TABLE III. Results of Generalized Linear Mixed Models for the Dichotomous Outcomes on Depression, Anxiety, and Suicidal Ideation

	Intake				Follow-up				Became Worse			
Effects	Odds Ratio	95% CI		*P* value	Odds Ratio	95% CI		*P* value	Odds Ratio	95% CI		*P* value
Depression												
Age	0.94	0.91	0.97	0.0002	0.97	0.94	1.01	0.0943	0.99	0.96	1.03	0.7131
Gender, female	1.73	1.39	2.16	<0.0001	1.64	1.30	2.08	<0.0001	1.62	1.22	2.15	0.0010
Race, others	0.85	0.67	1.08	0.1810	0.83	0.64	1.08	0.1630	0.81	0.58	1.12	0.1947
Education, college or higher	0.89	0.71	1.12	0.3275	0.79	0.62	1.01	0.0628	0.84	0.63	1.13	0.2585
Income ≥$35,000	0.87	0.63	1.18	0.3581	1.11	0.81	1.52	0.5066	1.40	0.98	2.00	0.0643
Time in Army 1–3 years	0.47	0.27	0.80	0.0058	1.45	0.77	2.73	0.2464	1.62	0.75	3.47	0.2170
Time in Army <1 year	0.52	0.35	0.77	0.0011	1.22	0.72	2.07	0.4604	1.32	0.70	2.52	0.3923
Navy/Air Force, no	0.56	0.32	0.97	0.0401	1.35	0.57	3.16	0.4951	1.96	0.60	6.34	0.2625
Active duty, yes	1.02	0.82	1.28	0.8529	1.26	0.99	1.61	0.0566	1.18	0.88	1.58	0.2712
Anxiety												
Age	0.94	0.91	0.97	<0.0001	0.97	0.94	1.00	0.0183	0.99	0.96	1.02	0.6044
Gender, female	1.39	1.15	1.68	0.0008	1.49	1.22	1.81	<0.0001	1.36	1.06	1.74	0.0151
Race, others	0.90	0.74	1.11	0.3252	0.83	0.67	1.02	0.0788	0.78	0.59	1.03	0.0763
Education, college or higher	0.86	0.71	1.05	0.1347	0.80	0.66	0.98	0.0272	0.87	0.68	1.12	0.2750
Income ≥$35,000	0.96	0.74	1.24	0.7458	0.90	0.69	1.17	0.4354	1.00	0.72	1.38	0.9811
Time in Army 1–3 years	0.65	0.41	1.02	0.0610	0.84	0.50	1.41	0.5042	0.71	0.35	1.45	0.3447
Time in Army <1 year	0.60	0.42	0.85	0.0043	1.10	0.73	1.65	0.6428	1.34	0.79	2.27	0.2730
Navy/Air Force, no	0.85	0.50	1.45	0.5484	1.01	0.55	1.86	0.9806	0.87	0.43	1.79	0.7082
Active duty, yes	1.00	0.82	1.20	0.9573	1.22	1.00	1.48	0.0456	1.19	0.93	1.52	0.1584
Suicidal Ideation												
Age	0.97	0.92	1.02	0.1812	0.96	0.92	1.01	0.1263	0.97	0.92	1.03	0.3135
Gender, female	1.13	0.80	1.61	0.4863	1.08	0.76	1.52	0.6828	1.06	0.70	1.60	0.7901
Race, others	1.13	0.79	1.61	0.5040	1.12	0.79	1.60	0.5283	0.99	0.65	1.52	0.9662
Education, college or higher	1.08	0.76	1.53	0.6736	1.06	0.76	1.50	0.7295	0.99	0.66	1.48	0.9660
Income ≥$35,000	0.70	0.42	1.16	0.1661	0.90	0.56	1.43	0.6396	1.14	0.68	1.92	0.6278
Time in Army 1–3 years	1.82	0.76	4.34	0.1775	2.71	0.96	7.64	0.0596	1.52	0.44	5.30	0.5125
Time in Army <1 year	1.10	0.52	2.32	0.8127	2.04	0.81	5.11	0.1307	1.89	0.67	5.31	0.2264
Navy/Air Force, no	1.03	0.37	2.88	0.9585	0.58	0.24	1.39	0.2236	0.65	0.23	1.87	0.4222
Active duty, yes	0.99	0.70	1.39	0.9567	1.57	1.11	2.22	0.0113	1.90	1.24	2.92	0.0034

The above findings were consistent with the results of linear mixed modeling of the continuous depression and anxiety scores. Table IV shows that, compared with soldiers enlisted more than 3 years in the Army, those enlisted less than 1 year were 1.30 points lower in the mean anxiety at time of intake, but 1.08 points higher in the mean depression change and 2.30 points higher in the mean anxiety change. These models also showed that female soldiers had a significantly higher level of depression and anxiety at time of intake and follow-up. Once again, older age was associated with less depression and anxiety at intake and at follow-up; while college or more education was associated with less depression at follow-up and less anxiety at both times. However, it should be noted that the sociodemographic and military factors together explained less than 3% of total variations in each of the three outcomes.

DISCUSSION

This study represents one of the few prospective, predeployment investigations of depression, suicidal ideation, and anxiety in the military. Unique features of the study include the investigation of the change in negative mood associated with AIT and the predictors of negative mood and change in mood in a military population. The rising incidence of mental health issues in military personnel, most likely the result of recent conflicts, highlights the need to investigate predisposing factors associated with mental health risk and the effects of training on mental health symptoms.

Our results suggest that at the time of entry into AIT, a substantial number of soldiers in training to become combat medics showed clinically significant levels of depression (10.4%) and anxiety (15.5%). In addition, over 4% endorsed suicidal ideation. These rates are relatively consistent with those associated with returning veterans[4] and entry-level military personnel.[1] Rates of suicide or prevalence of suicidal ideation involving the current military conflicts are not readily available and any direct comparisons of rates of suicidal ideation with suicide attempts or completed suicides should be made with caution. However, suicide ideation prevalence rates as high as 30% have been reported in deployment settings,[9] while suicide rates in Navy and Marine personnel ranged from 10 to 16 per 100,000 for the years 1999–2001.[10] The latter estimate of actual suicide rate in Navy and Marine personnel occurred in nonwartime deployment. The suicidal ideation reported in the present study is less than that reported in deployment settings; the increase in suicidal ideation at the end of AIT may reflect an increase associated with the possibility of impending deployment to combat, thus reflecting

TABLE IV. Results of Linear Mixed Models for the Continuous Outcomes on Depression and Anxiety

	Intake			Follow-up			Change		
	Estimate	SE	*P* value	Estimate	SE	*P* value	Estimate	SE	*P* value
Depression									
Intercept	8.65	1.04	<0.0001	8.14	1.39	<0.0001	0.59	1.25	0.6414
Age	−0.09	0.03	0.0011	−0.09	0.04	0.0189	0.01	0.03	0.8517
Gender, female	2.11	0.24	<0.0001	1.72	0.31	<0.0001	−0.15	0.28	0.5930
Race, others	0.05	0.24	0.8302	−0.44	0.32	0.1669	−0.59	0.29	0.0403
Education, college or higher	−0.09	0.23	0.7104	−0.61	0.30	0.0449	−0.68	0.27	0.0128
Income ≥$35,000	0.23	0.29	0.4334	0.21	0.38	0.5859	0.06	0.34	0.8632
Time in Army 1–3 years	−0.51	0.57	0.3683	0.78	0.74	0.2871	1.02	0.66	0.1230
Time in Army <1 year	−0.10	0.43	0.8215	0.74	0.57	0.1977	1.08	0.52	0.0368
Navy/Air Force, no	−0.88	0.61	0.1506	−0.65	0.86	0.4517	−0.65	0.78	0.4024
Active duty, yes	0.08	0.23	0.7230	0.57	0.30	0.0532	0.41	0.27	0.1215
Anxiety									
Intercept	42.78	1.44	<0.0001	42.81	1.87	<0.0001	0.28	1.52	0.8530
Age	−0.21	0.04	<0.0001	−0.16	0.05	0.0015	0.05	0.04	0.2500
Gender, female	1.72	0.33	<0.0001	1.87	0.42	<0.0001	0.44	0.34	0.1958
Race, others	−0.22	0.33	0.5110	−0.55	0.44	0.2045	−0.32	0.35	0.3615
Education, college or higher	−1.10	0.32	0.0005	−1.23	0.41	0.0027	−0.34	0.33	0.3151
Income ≥$35,000	−0.43	0.41	0.2875	−0.91	0.52	0.0809	−0.31	0.42	0.4645
Time in Army 1–3 years	−1.50	0.78	0.0565	−0.44	0.99	0.6548	1.08	0.81	0.1798
Time in Army <1 year	−1.30	0.60	0.0312	0.35	0.78	0.6548	2.30	0.63	0.0003
Navy/Air Force, no	−0.86	0.85	0.3106	−2.40	1.17	0.0397	−1.72	0.95	0.0694
Active duty, yes	0.04	0.31	0.9034	0.45	0.40	0.2629	0.26	0.32	0.4136

a continuum from nonwartime, to predeployment, to combat deployment.

Soldiers with less experience (shorter military service, no other service history) were slightly less likely to have clinically significant depression. However, duration of military service was not a significant predictor of depression or anxiety at the end of AIT. Examination of the changes within each group suggests that initial distress increased for those with less experience, while those with previous military history adjusted better (depression decreased) to the impending deployment as AIT progressed.

A different pattern emerged at post-AIT. Full-time active duty service members were more likely to have clinically significant depression and anxiety, as well as suicidal ideation, at the end of AIT. One potential explanation is that active duty personnel may have had greater experience with combat stressors and thus had higher anticipated distress as imminent deployment approached. The increased rate of distress in this group argued against a preventive function of AIT. The design of this study prevents definitive conclusions about the effects of AIT, but these speculations suggest further investigation with appropriate control for type of training might be fruitful.

Women were more likely to be depressed and anxious and to transition from subclinical to clinical levels of distress than were men. These findings are generally consistent with the larger literature on sex differences in negative affect.[7] As the number of women in the military increases, so does the importance of recognizing this increased risk. Increased age and greater education appeared to be somewhat protective and were associated with decreased risk of depression and anxiety. However, these effects were not consistently observed at all time points and appeared relatively small in magnitude.

The same general pattern of results was observed whether the outcome variables were treated as dichotomous (clinically significant or not) or continuous, suggesting that the findings are relatively stable and not an artifact of the specific clinical cutoffs employed for this particular analysis. Overall, when considered as continuous variables, the magnitudes of observed differences during AIT are small and probably not clinically significant. The mean values for depression and anxiety are well below clinical cutoffs associated with a diagnosis of depression or anxiety, which may be a reflection of a general reticence of military personnel to report mental health symptoms.[11]

There are a number of limitations to this study. The study was not originally designed to assess trends in mental health issues in the military. The parent study was designed to test hypotheses about intervention to prevent back pain in military personnel and included the mood measures as predictors and descriptive data for that purpose. Because this report represents a secondary, exploratory analysis, a number of potential explanatory variables were not available for analysis. Furthermore, there was no experimental manipulation (e.g., treatment) related to negative mood, and the resulting data are correlational in nature with all the associated limitations about causality inferences. Our sample also appears to be relatively highly educated (53% with college education) and therefore combat medics may not be representative of the general army

population on that variable. This fact is especially important given that education is associated with lower rates of distress in this data set.

In summary, these data are consistent with reports of depression, anxiety, and suicidal ideation in military personnel. We have identified both demographic (i.e., age, sex) and military-specific predictors (i.e., duty status, history of military service) of psychological distress in soldiers undergoing combat medic training. These longitudinal data add to the existing literature by suggesting that as possible combat deployment is imminent, distress increases were also evident. AIT may be a time when preventive measures could be implemented or more tailored to the identified predictors. Further research designed to specifically investigate the identified predictors in other military populations, and with specific interventions, appear warranted. These could include better diagnostic criteria for depression and anxiety (particularly PTSD), longer follow-up to include suicide attempt data, a greater diversity of comparison groups/cohorts, and designs better able to infer causal relationships.

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ORIGINAL ARTICLE

Psychosocial education improves low back pain beliefs: results from a cluster randomized clinical trial (NCT00373009) in a primary prevention setting

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Abstract The general population has a pessimistic view of low back pain (LBP), and evidence-based information has been used to positively influence LBP beliefs in previously reported mass media studies. However, there is a lack of randomized trials investigating whether LBP beliefs can be modified in primary prevention settings. This cluster randomized clinical trial investigated the effect of an evidence-based psychosocial educational program (PSEP) on LBP beliefs for soldiers completing military training. A military setting was selected for this clinical trial, because LBP is a common cause of soldier disability. Companies of soldiers ($n = 3{,}792$) were recruited, and cluster randomized to receive a PSEP or no education (control group, CG). The PSEP consisted of an interactive seminar, and soldiers were issued the *Back Book* for reference material. The primary outcome measure was the back beliefs questionnaire (BBQ), which assesses inevitable consequences of and ability to cope with LBP. The BBQ was administered before randomization and 12 weeks later. A linear mixed model was fitted for the BBQ at the 12-week follow-up, and a generalized linear mixed model was fitted for the dichotomous outcomes on BBQ change of greater than two points. Sensitivity analyses were performed to account for drop out. BBQ scores (potential range: 9–45) improved significantly from baseline of 25.6 ± 5.7 (mean ± SD) to 26.9 ± 6.2 for those receiving the PSEP, while there was a significant decline from 26.1 ± 5.7 to 25.6 ± 6.0 for those in the CG. The adjusted mean BBQ score at follow-up for those receiving the PSEP was 1.49 points higher than those in the CG ($P < 0.0001$). The adjusted odds ratio of BBQ improvement of greater than two points for those receiving the PSEP was 1.51 (95% CI = 1.22–1.86) times that of those in the CG. BBQ improvement was also mildly associated with race and college education. Sensitivity analyses suggested minimal influence of drop out. In conclusion, soldiers that received the PSEP had an improvement in their beliefs related to the inevitable consequences of and ability to cope with LBP. This is the first randomized trial to show positive influence on LBP beliefs in a primary prevention setting, and these findings have potentially important public health implications for prevention of LBP.

Keywords Primary prevention · Patient education · Biopsychosocial · Public health

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Introduction

Low back pain (LBP) is a common chronic musculoskeletal disorder [19, 32] that causes significant disability [2, 31, 33, 40]. Specifically, LBP has been associated with the inability to obtain or maintain employment [31] and lost productivity while still employed [33]. Cost-effective interventions for LBP are a research priority given its adverse impact on society [10]. Providing evidence-based education is one example of a cost-effective intervention for LBP.

Educational approaches based solely on anatomical explanations of LBP are known to be inadequate given the contemporary understanding of a biopsychosocial conceptualization of LBP [17, 26, 37]. Currently, it is recommended that patient education for LBP de-emphasizes the anatomical cause of the pain, encourages the patient to focus on resuming activity, teaches the patient to view LBP as a common condition, and reinforces the importance of maintaining positive attitude and coping styles [36, 38].

This change in education approach has had a positive influence on management of existing LBP. For example, advice to stay active and resume normal activities was more effective than usual medical care for LBP in separate randomized trials [14, 15, 18]. Psychosocial education that encourages positive coping was associated with decreased work absence in a quasi-experimental study [34]. The *Back Book* [27] is a pamphlet that delivers standard, evidenced-based information consistent with a biopsychosocial model, and has been used in randomized clinical trials demonstrating reduced disability and fear-avoidance beliefs in general practice [8] and physical therapy settings [12]. A quasi-experimental study also indicated that general practice patients given the *Back Book* reported higher patient satisfaction ratings and lower rates of persistent LBP [10].

Although these secondary prevention findings are important, less evidence is available to inform decision-making regarding whether psychosocial education can be effective in primary prevention of LBP. In an effective primary prevention model, evidence-based information would alter unwarranted beliefs about the consequences and management of LBP, as well as reduce the fear and threat of experiencing LBP. Understanding whether favorably altering beliefs about LBP before LBP develops has become a critical research priority given the huge cost burden of LBP on society [3, 20] and the pessimistic views held by the general population about the consequences of LBP [13].

Several population-based studies have investigated the primary prevention effects of psychosocial information on LBP delivered by media campaigns [6, 7, 39, 43]. Collectively these studies demonstrated a positive shift in LBP beliefs [6, 7, 39, 43], with persistent effects noted 3 years later by Buchbinder et al. [5]. Although these results are encouraging, these population-based studies utilized quasi experimental [7, 43] and "pragmatic observational" [39] methodologies; no randomized trials have been reported to date. Therefore, the purpose of this paper is to report the effect of an evidence-based PSEP on LBP beliefs for soldiers completing military training and participating in an ongoing cluster randomized clinical trial. This particular setting was selected for this study, because disability from LBP is commonly experienced in the military [16, 29] and favorable shifts in LBP beliefs before LBP is experienced could potentially alter this trend.

Materials and methods

Overview

The institutional review boards at the Brooke Army Medical Center (Fort Sam Houston, TX, USA) and the University of Florida (Gainesville, FL, USA) granted approval for this project. Consecutive soldiers entering the combat medic advanced individual training (AIT) at Fort Sam Houston, TX were considered for participation in this study. This study reported a planned analysis of a proximal outcome of the prevention of low back pain in the military (POLM) clinical trial (NCT00373009) [11] which has been registered at http://clinicaltrials.gov.

The goals of this study were to twofold. First, we wanted to determine the efficacy of an implemented PSEP for improving LBP beliefs. Second, we wanted to investigate the potential of responder subgroups to the PSEP. Our a priori hypothesis was that soldiers receiving the education program would have an improvement in LBP beliefs, in comparison to those that not receiving the education program. We also investigated whether demographic or psychological factors were predictive of improvement in LBP beliefs to identify responder subgroups.

Subjects

Research staff at Fort Sam Houston, Texas introduced the study to individual companies of soldiers. Soldiers were screened for eligibility, and informed consent was obtained, as appropriate. For 12 consecutive months soldiers were screened for eligibility according to the following inclusion/exclusion criteria.

Inclusion criteria

- age 18 (or emancipated minor that is 17-year-old) to 35-year-old,

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- participating in combat medic military occupational specialty (MOS) training,
- English speaking and reading.

Exclusion criteria

- prior history of LBP (operationally defined as LBP that limited work or physical activity, lasted longer than 48 h, and caused the subject to seek healthcare) or previous medical history for any surgery for LBP,
- currently seeking medical care for LBP,
- history of degenerative joint disease, arthritis, spine trauma or vertebral fractures, and/or spondylolisthesis,
- currently unable to participate in physical fitness training due to injury in foot, ankle, knee, hip, neck, shoulder, elbow, wrist, or hand injury,
- history of fracture (stress or traumatic) in proximal femur and/or pelvis,
- currently pregnant,
- previous failure of AIT.

Randomization

Military training environments requires living in close quarters with other members of the unit making individual randomization an unfeasible option for this trial due to concerns related to disruption of normal training schedule and treatment contamination. Therefore, a cluster randomization strategy was utilized for assigning companies to receive or not receive the PSEP. This meant that for a given company, every soldier who consented to the study received the same study condition. Cluster randomization is viable methodological choice that has been effectively used in other large samples of primary prevention [23, 24, 42]. The randomization schedule was prepared by computer and was determined before recruitment began. The randomization schedule was balanced to ensure equal allocation to each condition after 18 companies were recruited.

Intervention

Companies of soldiers were randomized to receive or not receive the PSEP. It was not possible to mask soldiers in this study, because of the nature of the educational program. The interventions are described below.

Psychosocial educational program (PSEP)

The PSEP involved an educational session within the first 14 days of entering AIT. The session consisted of an interactive seminar designed by the POLM investigative team and was implemented by study personnel. The overall goal of the 45-min session was to emphasize current scientific evidence on LBP. The seminar covered topics related to the favorable natural history of LBP, lack of definitive anatomical causes of LBP, the importance of returning to normal activity, and decreasing fear-avoidance beliefs and pain catastrophizing when experiencing LBP. After the seminar, soldiers were involved in a question and answer session and issued *The Back Book* [27]. *The Back Book* was used as the educational supplement, because of our prior experience with it in a physical therapy clinical trial [12] and its prior association with positive shifts in patient LBP beliefs [8, 10].

Control group (CG)

The CG received no formal instruction on LBP. An anatomy-based education program was not appropriate for a comparison, because prior studies have demonstrated no favorable change in LBP beliefs [8, 12, 34]. Furthermore, use of a CG (as opposed to an alternate form of education) is consistent with the methodology from the previously reported population-based studies [6, 7, 39, 43].

Measurement

Study-related measures were collected by research personnel unaware of randomization assignment before AIT and 12 weeks later, when AIT was completed. All measures were scored in a masked manner by computer algorithm.

Primary outcome measure

The back beliefs questionnaire (BBQ) was the primary outcome variable for this study. The BBQ is a previously validated self-report questionnaire used to quantify beliefs about the likely consequences of having LBP [35]. The BBQ has 14 items with response options ranging from 1 (agree) to 5 (disagree), and only the nine inevitability items are included for scoring (potential range: 9–45). Higher BBQ scores are indicative of better LBP beliefs and indicate the potential of a better ability to cope with LBP [6, 7]. In addition to having sound psychometric properties, the BBQ has been used as an outcome measure in other studies investigating educational and mass media interventions [5–7, 34]. Use in this trial is appropriate for our hypotheses and will also allow for cross-study comparisons.

Other measures

Commonly implemented and previously validated self-report questionnaires were used to compare baseline

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attributes for the intervention groups and to determine baseline influence on LBP belief outcomes. The medical outcomes survey 12-item short-form health survey (SF-12) was used as a self-report of health status for physical and mental function. The physical and mental component summary scales (PCS and MCS) were reported individually in this study because they are valid estimates of physical and mental health [41]. The state-trait anxiety questionnaire (STAI) [30] and Beck depression inventory (BDI) [9, 28, 44] were used to measure negative affect from generalized anxiety and generalized depression, respectively. Nine items from the fear of pain questionnaire (FPQ-III) were used to measure fear about specific situations that normally produce pain [1, 21, 25].

Sample size estimation

In a previous study from Buchbinder et al. [5.], it was estimated that a sample size of 550 provided 80% power to detect a shift in BBQ of 0.5 (at 0.05 significance). Our primary sample size estimation was based on determining the effect of education and exercise programs on the occurrence and severity of LBP episodes [11]. Such a sample size (16 companies, approximately 3,200 soldiers) provided adequate statistical power for the planned proximal outcome analysis of LBP beliefs, as well as the consideration of responder subgroups from various demographic and psychological factors.

Data analysis

Demographic and baseline levels of variables were compared between the two randomly assigned groups using *t* test for comparison of means and chi-square tests for comparison of proportions. It was determined a priori that variables significantly different between the two groups would be considered in the final analyses, in addition to previously specified covariates of sex, age, and race.

First, we analyzed the 12-week follow-up completers only, as a liberal estimate of treatment effect. A linear mixed model was fitted for the BBQ at the 12-week follow-up in continuous scale, and a generalized linear mixed model was fitted for the dichotomous outcomes on BBQ change of more than two points. Two points was selected as a criterion of meaningful change in the BBQ, because it corresponded with previously reported thresholds in the literature such as 2-year population changes in BBQ scores that were associated with improvements in worker's compensation claims [7]. There was no sample-specific cut-off scores available for this part of the analysis, as the BBQ has not been previously studied in military samples.

A sensitivity analysis regarding missing data was conducted with the following 3-step process: (1) the dropout rates were compared across the education programs to assess systematic differences; (2) demographic and baseline levels of variables were examined for their relationship to dropout. Those variables related to dropout status were used to impute missing values for use in the intention to treat analysis of all soldiers; (3) comparison of the completers versus imputation analyses would provide an additional estimate of the effect of dropouts on hypothesis tests. All statistical analyses were performed using the SAS software, version 9 (SAS Institute Inc, 1996).

Results

Refer to Fig. 1 for a flow chart describing the number of patients considered for this trial, eventually enrolled into the trial, and completed follow-up assessment, as per CONSORT guidelines [22]. Descriptive statistics for the sample ($n = 3{,}792$) are summarized in Table 1. There were small post randomization differences noted for the PSEP and CG, such that soldiers assigned to PSEP had worse BBQ scores, were older, more likely to have college level or more education, and more likely to have enlisted in the army for 1–3 years ($P < 0.01$). These variables were included as covariates in the subsequent analyses.

The BBQ score improved significantly ($P < 0.0001$) from baseline of 25.6 ± 5.7 (mean $\pm$ SD) to 26.9 ± 6.2 at the 12-week follow-up for those receiving the PSEP, while there was a significant decline ($P < 0.0001$) from 26.1 ± 5.7 to 25.6 ± 6.0 for those in the CG (Fig. 2). The effect sizes of BBQ change were 0.18 and -0.10, for the PSEP and CG groups, respectively. These differences favoring the PSEP for BBQ scores were statistically significant at the 12-week follow-up ($P < 0.0001$). Table 2 presents the results of linear mixed modeling of the BBQ at the 12-week follow-up and the results of generalized linear mixed models for the dichotomous outcomes of BBQ improvement (greater than two points). The adjusted mean improvement for those receiving the PSEP was 1.49 points higher than those in the 4CG ($P < 0.0001$). The adjusted odds ratio of BBQ improvement for those receiving the PSEP was 1.51 (95% CI = 1.22–1.86) compared to those in the CG.

BBQ score at intake, older age, female, race other than white, college education or higher are significantly associated with higher BBQ score at the follow-up. When psychological factors were investigated, only fear of pain and depression were statistically associated with BBQ follow-up score. These psychological associations were small in magnitude, as every unit increase in FPQ and BDI was associated with a 0.04 and 0.10 point lower follow-up BBQ score, respectively. The analyses investigating subgroup responder characteristics indicated potential

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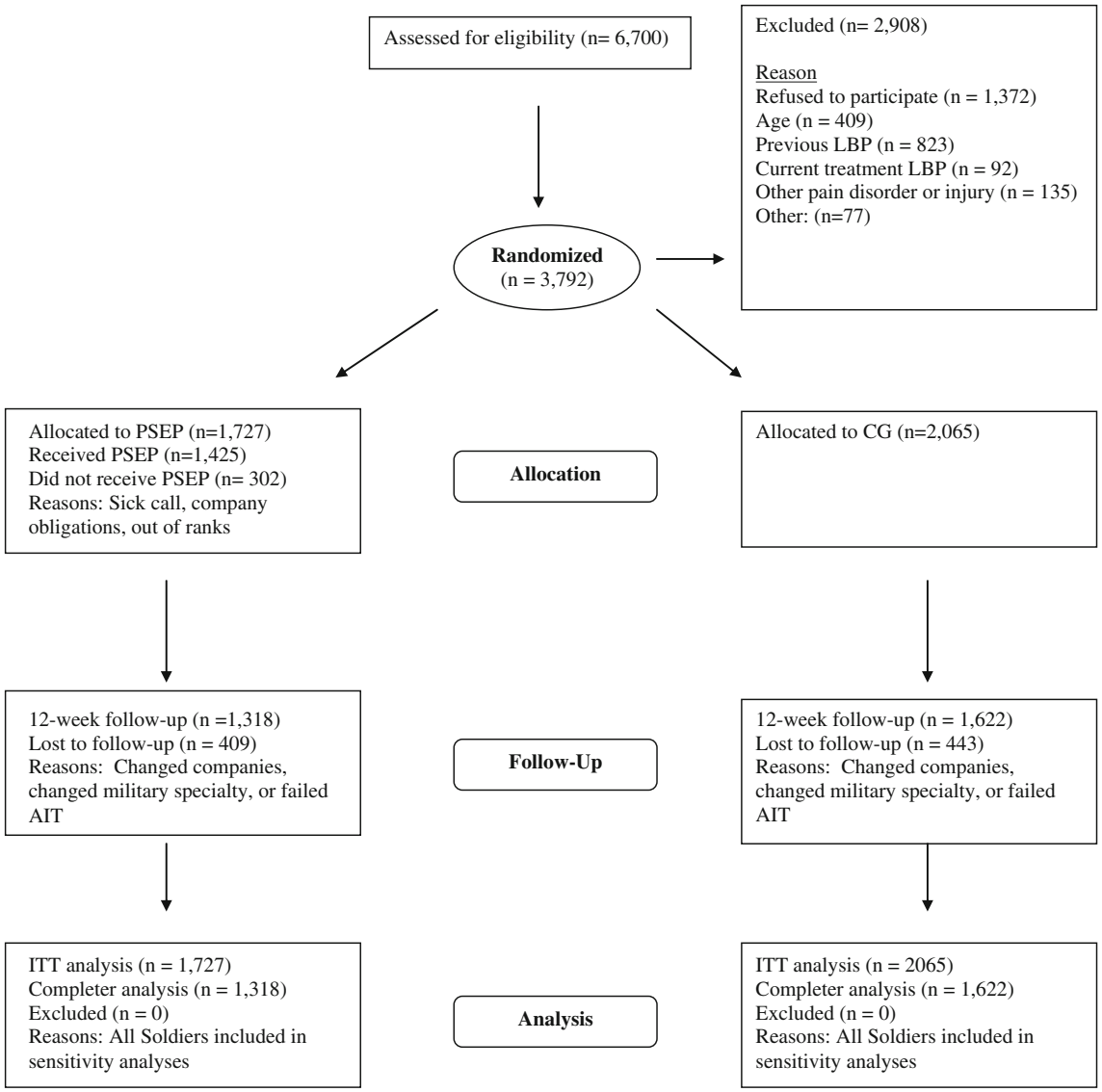

Fig. 1 Summary of recruitment, enrollment, follow-up, and analysis for psychosocial education trial. *LBP* low back pain, *PSEP* psychosocial education program, *CG* control group, *AIT* advanced individual training, *ITT* intention to treat analysis

demographic influences on BBQ scores (Table 2). BBQ improvement for soldiers of race other than white had an odds ratio of 0.82 (95% CI: 0.69–0.98). College education or higher was also related to BBQ improvement, with an odds ratio of 1.23 (95% CI: 1.05–1.44). In contrast, none of the psychological variables were associated with BBQ improvement of greater than two.

There were no major changes in results when the sensitivity analyses were performed, suggesting minimal influence of study drop out. The CG had a higher drop out rate than the PSEP group (25.7 vs. 19.8%). The drop outs from the two groups had the same intake characteristics, except that proportion of soldiers of race other than white in the CG was higher than that of the PSEP group. There were significant differences ($P < 0.05$) from the soldiers, who completed the follow-up ($n = 2{,}940$) at 12 weeks compared to those soldiers that dropped out ($n = 852$) in baseline BBQ, PCS, MCS, BDI, STAI, race, education level, and time enlisted in army. These variables were used to predict the BBQ at follow-up for those dropped out using a linear mixed model fitted based on complete data. Sensitivity analyses were then performed by running two separate models. The first model was an intention to treat analysis with all soldiers ($n = 3{,}792$) using the imputed outcome for those not completing follow-up. The second model was an analysis of the imputed outcome for only those soldiers ($n = 852$) not completing follow-up. In the intention to treat analysis, the adjusted mean BBQ scores at follow-up for those receiving the PSEP was 1.44 points higher than those in the CG ($P < 0.0001$), with an odds

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Table 1 Sociodemographic and psychological characteristics of the military sample

Factors	Intake (n = 3,792)			Missed 12-week follow-up (n = 852)		
	Total	CG (n = 2,065)	PSEP (n = 1,727)	Total	CG (n = 443)	PSEP (n = 409)
BBQ total [mean (SD)]	25.9 (5.7)	26.1 (5.7)	25.6 (5.7)*	25.4 (5.6)	25.7 (5.5)	25.2 (5.7)
PCS total [mean (SD)]	53.5 (5.1)	53.5 (5.2)	53.4 (5.1)	52.8 (5.6)	52.9 (5.4)	52.6 (5.8)
MCS total [mean (SD)]	49.1 (8.6)	49.2 (8.6)	49.0 (8.7)	47.7 (9.8)	48.3 (9.5)	47.0 (10.1)
FPQ total [mean (SD)]	18.1 (5.8)	17.9 (5.9)	18.3 (5.7)	18.1 (6.1)	17.7 (6.3)	18.5 (5.9)
BDI total [mean (SD)]	6.4 (6.6)	6.4 (6.7)	6.3 (6.5)	7.9 (8.0)	7.8 (8.0)	7.9 (8.0)
STAI total [mean (SD)]	36.0 (9.2)	35.9 (9.3)	36.0 (9.0)	37.7 (9.8)	37.6 (10.0)	37.8 (9.7)
Age [mean (SD)]	22.0 (4.4)	21.6 (4.2)	22.4 (4.6)*	21.9 (4.4)	21.6 (4.1)	22.2 (4.7)
Race [n (%)]						
Other	1,049 (27.7)	581 (28.1)	468 (27.1)	288 (33.8)	173 (39.1)	115 (28.1)*
White or Caucasian	2,743 (72.3)	1,484 (71.9)	1,259 (72.9)	564 (66.2)	270 (61.0)	294 (71.9)
Gender [n (%)]						
Female	1,103 (29.1)	625 (30.3)	478 (27.7)	252 (29.6)	144 (32.5)	108 (26.4)
Male	2,689 (70.9)	1,440 (69.7)	1,249 (72.3)	600 (70.4)	299 (67.5)	301 (73.6)
Education [n (%)]						
College or more	2,028 (53.5)	1,073 (52.0)	955 (55.3)	391 (45.9)	195 (44.0)	196 (47.9)
High school or less	1,764 (46.5)	992 (48.0)	772 (44.7)	461 (54.1)	248(56.0)	213 (52.1)
Income [n (%)]						
$35,000 or more	665 (17.6)	322 (15.6)	343 (19.9)*	143 (16.8)	63 (14.3)	80 (19.7)
Less than $35,000	3,118 (82.4)	1,738 (84.4)	1,380 (80.1)	706 (83.2)	379 (85.8)	327 (80.3)
Time in army [n (%)]						
1–3 years	322 (8.5)	153 (7.4)	169 (9.8)*	54 (6.3)	25 (5.6)	29 (7.1)
<1 year	3,199 (84.4)	1,794 (87.0)	1,405 (81.4)	733 (86.0)	386 (87.1)	347 (84.8)
>3 years	269 (7.1)	116 (5.6)	153 (8.9)	65 (7.6)	32 (7.2)	33 (8.1)

BBQ back beliefs questionnaire, *PSEP* psychosocial education program, *FPQ-III* fear of pain questionnaire, *BDI* Beck depression inventory, *STAI* state trait anxiety index, *PCS* physical component summary, *MCS* mental component summary

* $P < 0.01$ in t tests for comparison of means and chi-square tests for comparison of proportions between the two randomly assigned groups

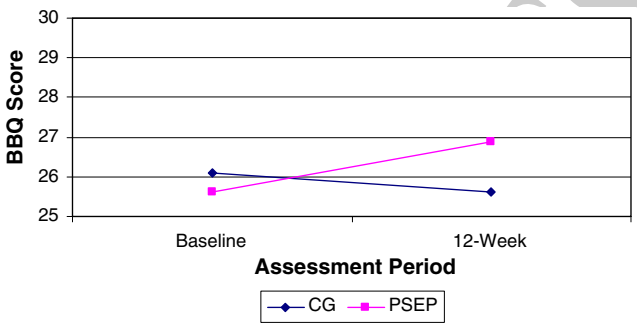

Fig. 2 Psychosocial education results in improvement in low back pain beliefs. *BBQ* back beliefs questionnaire, *CG* control group, *PSEP* psychosocial education program. Statistically significant differences were present at the 12-week assessment ($P < 0.0001$)

ratio for BBQ improvement of 1.75 (95% CI: 1.44–2.13). In the imputation outcome analysis the adjusted mean BBQ scores for those receiving the PSEP was 1.31 points higher than those in the CG ($P < 0.0001$), with an odds ratio for BBQ improvement of 2.10 (95% CI: 1.52–2.92).

Discussion

The general population has a pessimistic view on the consequences of LBP, and it has been hypothesized that such beliefs contribute to the development of disability from LBP [13]. Information that positively alters beliefs about LBP to better reflect current evidence has potential treatment implications in a variety of settings [7, 8, 10, 12, 39, 43]. Consecutive companies of soldiers were recruited for the current study, excluding those with a previous history of LBP or with a current musculoskeletal pain condition. Our findings suggested that for this cohort, the PSEP resulted in a small improvement in LBP beliefs and potential ability to cope with LBP. Our study included a CG that suggests the natural history of LBP beliefs is to slightly worsen in this particular environment. Although only a small effect size was associated with BBQ improvement, the current study adds to the existing literature as it is the first randomized trial to demonstrate positive influence on LBP beliefs in a primary prevention setting.

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Table 2 Summary of analyses results for low back pain beliefs

Effects	BBQ total at follow-up (continuous)			BBQ improvement (categorical)			
	Estimate	SE	*P* value	Odds ratios	95% CI		*P* value
Intercept	15.66	2.35	<0.0001				
BBQ total at intake	**0.41**	**0.02**	**<0.0001**				
PSEP	**1.49**	**0.22**	**<0.0001**	**1.51**	**1.22**	**1.86**	**0.0001**
Age	**0.06**	**0.02**	**0.0090**	1.01	0.99	1.03	0.1939
Gender: female	**0.84**	**0.24**	**0.0004**	0.90	0.76	1.07	0.2217
Race: others	−0.23	0.24	0.3271	**0.82**	**0.68**	**0.96**	**0.0128**
Education: college or more	**0.45**	**0.22**	**0.0401**	**1.23**	**1.05**	**1.44**	**0.0106**
Income: $35,000 or more	−0.13	0.28	0.6374	1.00	0.82	1.22	0.9722
Time in army: 1–3 years	0.51	0.54	0.3432	1.11	0.76	1.62	0.5814
Time in army: <1 year	−0.03	0.42	0.9516	0.95	0.71	1.27	0.7344
FPQ-III total at intake	**−0.04**	**0.02**	**0.0205**	1.00	0.99	1.02	0.5859
BDI total at intake	**−0.10**	**0.02**	**<0.0001**	0.99	0.97	1.01	0.1905
STAI total at intake	−0.01	0.02	0.7679	1.01	0.99	1.02	0.3146
PCS total at intake	0.00	0.02	0.8621	1.00	0.98	1.02	0.9922
MCS total at intake	−0.02	0.02	0.1889	1.00	0.99	1.01	0.9270

Continuous outcome was calculated by raw change score and categorical outcome was defined as yes/no depending whether BBQ score increased more than two points from time of intake to follow-up. Statistically significant predictors are indicated in bold font ($P < 0.05$)

BBQ back beliefs questionnaire, *PSEP* psychosocial education program, *FPQ-III* fear of pain questionnaire, *BDI* Beck depression inventory, *STAI* state trait anxiety index, *PCS* physical component summary, *MCS* mental component summary

These results are consistent with earlier findings on improving LBP beliefs from population-based studies that used quasi-experimental or observational designs in Australia [5–7], Scotland [39], and Norway [43]. Although the evidence-based educational messages regarding LBP were likely similar across all studies, the current study incorporated one time, group instruction as compared to information delivered by radio, television, or print advertisements. The current study had the shortest follow-up time (12 weeks), while previously reported studies had follow-up times up to 3 years. Despite these methodological differences, there appears to be converging evidence that LBP beliefs can be effectively altered with evidence-based information delivered by a variety of mediums.

The relevance of the observed improvement in LBP beliefs is an important consideration when interpreting the results of this trial; yet definitive clinically important thresholds for BBQ change have not been reported. We utilized a BBQ change criterion based on the initial Buchbinder et al. [6, 7] studies that reported that a 2-year mean BBQ change of 1.9 was associated with decreased rates of compensation claims [7]. In contrast, we reported a smaller mean improvement of 1.5 in BBQ scores at 12 weeks. This smaller magnitude of change and earlier outcome assessment indicate a smaller potential for affecting future reports of disability and pain [7]. One reason for a smaller effect size in the current trial could be that the previously reported study [7] utilized quasi-experimental methodology, which has the potential to overestimate treatment effects [4]. Other equally plausible reasons for the smaller effect size observed in our study include the previously mentioned differences in study populations, and the mass media campaign by Buchbinder et al. [7] was more effective than a single session PSEP.

Another part of our analysis was to determine if demographic predictors of success existed, suggesting the potential for responder subgroups to exist. These analyses indicated that soldiers of race other than white were less likely to report a BBQ improvement (OR = 0.82), while those with college education or higher were more likely to report a BBQ improvement (OR = 1.23). These results suggest the potential of cultural or socioeconomic influences on the alteration of LBP beliefs. We are hesitant to speculate further on these influences, because these findings are preliminary and their theoretical implications are beyond the scope of the current manuscript. The only other available report is from Buchbinder et al. [5], who have reported similar levels of BBQ improvement across most demographic factors, with only upper white-collar workers having larger BBQ changes. Additional research is necessary to replicate these findings and determine if race or education status can be used to identify LBP belief responder subgroups.

Previous studies have not considered psychological factors, and our study suggests that fear of pain and depression was predictive of BBQ follow-up scores.

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However, these associations were quite small, suggesting these baseline psychological factors have only a minimal influence on BBQ outcome. Contrary to our expectations, baseline psychological factors were not associated with BBQ change greater than two. Psychological distress has been consistently associated with the development of chronic LBP [17, 26], and we expected those with higher pre-morbid levels of anxiety, depression, and fear of pain to have a stronger association with BBQ improvement. However, this was not the case in the current trial, as only weak statistical associations with follow up scores existed. A possible explanation for these unexpected findings could be that psychological distress levels were very low in this particular setting (Table 1), and these low levels had minimal potential to influence LBP beliefs. Another explanation is that the psychological factors of interest have a strong influence on LBP beliefs but only when individuals are actively experiencing LBP. Overall the responder analyses suggest that for this setting the PSEP intervention should not be considered for targeted application to psychological subgroups. However, future studies in different primary prevention cohorts with wider ranges of psychological distress are necessary to further investigate this issue.

The primary limitation of this study is that we did not investigate the LBP beliefs after 12 weeks or the effect of the PSEP on subsequent reports of pain, disability, and health care utilization. Pain, disability, and health care utilization are important outcomes to consider and these will be considered as 2-year endpoints in the ongoing POLM trial [11]. PSEP effect on LBP beliefs was an important factor to establish before determining pain, disability, and health care utilization as distal outcomes, because previous studies on the topic had not used randomized trial methodology. Another limitation is that this study was performed in a military setting, while the other studies in this area were performed with general populations. Although disability from LBP is a major problem across both of these settings, caution should be used when attempting to generalize our results to the general population. The use of a CG allowed us to determine the 12-week natural history of LBP beliefs, but it is also another limitation of this study. The effects of this particular PSEP are in reference to the CG, not a comparison education session.

Conclusion

This is the first randomized trial to show positive influence on LBP beliefs following a PSEP implemented in a primary prevention setting. In contrast, LBP beliefs slightly deteriorated for those in the CG. Though only small effect sizes were observed, these findings have potentially important public health implications for prevention of LBP. Future study will involve continuing the POLM trial to collect reports of LBP occurrence, severity, and health care utilization over the next 2 years [11]. These endpoints will allow us to make broader conclusions about the effectiveness of the PSEP for clinical presentation of LBP. Future study will also involve providing the same PSEP to health care providers and determine whether it positively influences professional advice given for treatment of LBP. Last, the same PSEP could be investigated to determine if it has public health implications for environments outside of the military, for example its effects on LBP beliefs in schools, universities, occupational, or clinical settings.

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